

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTES**

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**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

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## **1. Introduction to the Agreement**

### **1.1 Brief Description of the Project and Its Purpose**

This agreement concerns a pharmaceutical research facility which the Ortho-McNeil Pharmaceutical Corporation, in conjunction with the R. W. Johnson Pharmaceutical Research Institute (hereinafter "OMP", unless otherwise specified), operates in Spring House, Pennsylvania, and is reached pursuant to the Environmental Protection Agency's (EPA's) Project XL. Project XL (eXcellence and Leadership) comprises an initiative of EPA's under which potential Project Sponsors are encouraged to propose new approaches to environmental protection that can advance our nation's environmental goals more effectively and efficiently than current regulatory and policy tools or procedures.

OMP conducts pharmaceutical research and development at its research facility in Spring House, Pennsylvania. In order to meet the Food and Drug Administration's requirements for studying the safety and efficacy of new pharmaceuticals in the human body, OMP uses drugs "labeled" (marked) with radioisotopes, which enables the drugs' bioabsorption and metabolism in the body to be tracked with precision. This project concerns the handling of small quantities of OMP laboratory sample wastes which contain tritium ( $^3\text{H}$ ) and carbon-14 ( $^{14}\text{C}$ ), which OMP uses as tracers in its research due to the relatively low radiotoxicity of these radioisotopes and because they naturally occur in the environment. OMP is licensed by the Nuclear Regulatory Commission (NRC) to handle radioactive materials in its laboratories. (Copy of the license is attached as Appendix J. The NRC's existing controls on OMP's operations are unaffected by this project.)

OMP's research process produces small quantities of waste solutions containing solvents and radiolabeled material. The organic component of these wastes is a "hazardous waste" regulated by EPA under the Resource Conservation and Recovery Act (RCRA), and the radioactive component of these wastes is regulated by the NRC as a "low-level waste" (LLW) under the Atomic Energy Act (AEA) of 1954. This combined waste, termed "low-level mixed waste" (LLMW), is subject to regulations by both EPA and the NRC.

The quantities of LLMW generated by OMP are relatively small. Each "batch" of LLMW generated by OMP at its Spring House facility typically ranges from less than 50 milliliters to several liters in volume; yearly OMP generates less than 50 liters of LLMW in total. The amount of radioactive materials contained in this LLMW is also quite small. (As a condition of its NRC license, the NRC requires that OMP have no more than 50 curies (Ci) of tritium; 4 Ci of carbon-14; and 5 Ci total of any other byproduct material with Atomic Nos. 3 - 83 on hand at any one time). (Further details about the

nature and amount of radioactive material handled by OMP, and the regulatory framework which governs LLMW in Pennsylvania, is presented below).

Presently, the only permitted treatment option for LLMW, such as OMP's, involves off-site transportation and disposal at a Treatment, Storage and Disposal facility (TSDF) licensed by the NRC and permitted under RCRA. Commercially permitted TSDFs utilize incineration to treat LLMW wastes, which destroys the RCRA "hazardous waste" component of the LLMW, or solidification and land burial. Under either disposal methodology, the radioactivity contained in the LLMW is not recovered for reuse.

OMP proposes to achieve environmental performance superior to currently available practices through the use of a bench-scale high-temperature catalytic oxidation (HTCO) process which destroys the RCRA "hazardous waste" component of the LLMW and traps the remaining low-level radioactive material on-site, all within the same NRC-regulated laboratory in which the material is generated. OMP has been operating this process since 1996 as part of a treatability study approved by the Pennsylvania Department of Environmental Protection (PADEP) under its Solid Waste Management Act, 35 P.S. §§6018.101 – 6020.1304 (SWMA).

OMP is pursuing this XL Project, including the attendant stakeholder process, to assure greater regulatory certainty from the EPA as well as PADEP. PADEP and EPA are in support of this XL Project.

### ***Benefits of the High-Temperature Catalytic Oxidation Process***

OMP's high-temperature catalytic oxidation process appears to represent an environmentally superior way to address small quantities of LLMW in several respects. First, since waste is processed in the same secure, NRC-licensed laboratory where it is created, the risk of off-site spills, worker exposures, and releases during storage, transportation, and handling, while minimal when managed pursuant to RCRA, are further reduced. Second, the radioactive components are captured (in the form of radioactive carbon dioxide or tritiated water) rather than being lost through the incineration process (e.g., through incorporation in air pollution control media that is disposed of), and consequently providing a somewhat homogenous and consistent waste stream that is amenable to recycling and reuse.

Additionally, OMP has shared, and commits to continuing to share, this technology freely. This technology has broad application to other research institutions, government agencies such as the National Institutes of Health (NIH), colleges and universities, and hospitals that also generate LLMW. OMP has funded the travel of several of its scientists to conferences,

educational institutions, and private facilities to facilitate the broadest possible distribution of this technology. (See Appendix I)

Through this XL Agreement, OMP is seeking further regulatory certainty for its LLMW treatment process. Pursuant to this XL Project, OMP would continue to not be required to obtain a permit under RCRA for its LLMW catalytic oxidation process. However, OMP's LLMW would remain a RCRA solid waste, and be subject to other RCRA authorities, including EPA's authority to issue orders under Section 7003 (which addresses situations of "imminent and substantial endangerment to health or the environment").

## **1.2 Description of the Ortho-McNeil Facility / Community / Geographic Area**

The OMP Spring House facility occupies 172 acres in Spring House, Lower Gwynned Township, Montgomery County, Pennsylvania. The main facility comprises 758,000 sq. ft. of building space. The Spring House facility also includes a man-made stormwater retention pond used for firefighting and landscaping purposes, tennis courts, a baseball field, an exercise trail and a guest house. The facility was constructed in 1980 on land previously used as farmland and is bordered by Rohm & Haas to the West, a farm to the North, and residential areas and country clubs to the South and East.

The OMP Spring House facility houses four separate operating companies: Ortho-McNeil Pharmaceutical (OMP), the R. W. Johnson Pharmaceutical Research Institute (PRI), the Janssen Research Foundation (JRF) and Advanta Corporation. OMP, PRI and JRF are divisions of Johnson & Johnson, while Advanta, a financial services company, is an unrelated company that leases space in the building. OMP is the owner and landlord of the facility and provides engineering and maintenance support for PRI and JRF. OMP also operates a small manufacturing plant that produces PANCREASE® (pancrelipase) Capsules (used for the treatment of exocrine pancreatic enzyme deficiency in patients with cystic fibrosis) and VASCOR® (bepidil hydrochloride) Tablets (used for the treatment of chronic stable angina). Both PRI and JRF perform pharmaceutical-related research & development, including discovery and clinical and non-clinical development at the Spring House facility.

## **1.3 Purpose of the Agreement**

This Final Project Agreement ("the Agreement") is a joint statement of the plans, intentions and commitments of the EPA, PADEP, and OMP to carry out this pilot Project at OMP's Spring House facility. This Project will be part of EPA's Project XL program to develop innovative approaches to environmental protection.

This Agreement does not create legal rights or obligations and is not an enforceable contract or a regulatory action such as a permit or a rule. (The previous statement applies to both the substantive and the procedural provisions of this Agreement.) While the parties to the Agreement fully intend to follow these procedures, they are not legally obligated to do so. The parties do anticipate that both EPA and PADEP will issue a site-specific rule(s) and/or permit(s) applicable to OMP's facility, through which the regulatory flexibility sought by OMP will be achieved, which will also contain conditions that OMP must meet and maintain. For more details, please refer to Section 6 – Legal Basis for the Project.

All parties to this Agreement will strive for a high level of cooperation, communication, and coordination to assure successful, effective, and efficient implementation of the Agreement and the Project.

#### **1.4 List of Parties Who Will Sign the Agreement**

The Parties to this Final Project XL Agreement are:

- 1) The United States Environmental Protection Agency
- 2) The Pennsylvania Department of Environmental Protection
- 3) Ortho-McNeil Pharmaceutical

#### **1.5 List of Project Contacts**

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**2. Detailed Description of the Project**

**2.1 Summary of the Project**

Ortho-McNeil proposes to achieve environmental performance superior to currently available practices through the use of a bench-scale high-temperature catalytic oxidation (HTCO) process which destroys the RCRA "hazardous waste" component of the LLMW and traps the remaining low-level radioactive material on-site, all within the same NRC-regulated laboratory in which the material is being handled.

Following the application of the catalytic oxidation process, one of two types of treatment residue remains. When the sample had used tritium as the radioisotope tracer, the remaining low-level radioactive material is trapped in the form of low-level radioactive water utilizing cryogenic traps to condense the emissions from the process. When carbon-14 is used as the radioisotope tracer, the remaining low-level radioactive material is in the form of low-level carbon dioxide, which is passed through a 45% potassium hydroxide solution and converted to potassium carbonate solution. According to OMP, the HTO process has proven to be extremely effective in treating a broad range of organic solvents and has routinely achieved destruction removal efficiencies ("DRE") of 99.999 to 99.99999%. A more detailed description of the elements of the process is discussed in Section 2.2 below.

See Appendix A for a Simplified Schematic of the High Temperature Catalytic Oxidation Process.

See Appendix B for a list of hazardous organic components and the corresponding DRE achieved by the oxidation process.

## **2.2 Description of the Specific Project Elements**

### ***2.2.1 Project Element # 1 - Generation of Low-Level Mixed Waste***

The generation of LLMW is an unavoidable result of pharmaceutical research, which involves the study of the safety of drug compounds in the human body, given the FDA's requirements of the use of radioactive tracers in such research. During these studies, carbon-14 and tritium-labeled compounds are synthesized for use in the development of potential new therapeutic compounds. These syntheses generate millicurie (mCi) to Curie (Ci) quantities of LLMW test samples containing a wide variety of hazardous organic materials which are classified as "hazardous waste" under RCRA (see Appendix F for an explanation of the units of measurement of radioactivity). These consist of contaminated aqueous mixtures and various organic solvents, intermediates, and reagents used in the synthesis and purification of radiolabeled samples. The organic components include hydrocarbons, halocarbons, acetonitrile, alcohols, ethers, and aromatic compounds. A single preparation involves volumes ranging from less than 50 mL to several liters.

### ***2.2.2 Project Element # 2 - High-Temperature Catalytic Oxidation***

As an alternative to long-term storage of radioactive hazardous materials at its facility, or the off-site transportation and disposal of this waste at an NRC licensed, RCRA permitted TSDF, OMP has developed a bench-scale, high-temperature catalytic oxidation process to destroy the organic components of its mixed waste test samples as they are generated. In this process, the

liquid LLMW is completely reacted with oxygen or air at high temperature in the presence of an oxidation catalyst. The spent test samples are passed through an electrically heated, stainless steel tube packed with platinum catalyst. Heat is provided using a tube furnace equipped with three separately controlled heating zones. Liquid samples are blended and pumped into the heated catalyst tube using a pair of high performance liquid chromatography (HPLC) pumps. An electronic safety supervisor system monitors critical pressures and temperatures during operations and automatically turns the pumps off if an unsafe condition develops. The entire process is operated under a fume hood with continuous air monitoring (see details in Section 3.7.1.3). (A detailed description of the catalytic oxidation process is included in Appendix G.)

### ***2.2.3 Project Element # 3 - Trapping and Recovery of Effluents***

After passing through the heated zone, water and the radiolabeled reaction product (tritiated water or carbon-14-labeled carbon dioxide, depending on the radioisotope used as the tracer) are collected, free of hazardous organic chemicals, using appropriate pressure-tight traps. For tritium-labeled test samples, a series of three dry ice-cooled traps are used. Carbon-14-labeled carbon dioxide is scrubbed through a series of four gas washing bottle traps containing a 45% solution of potassium hydroxide. The trapped samples may be passed through the process again to achieve higher destruction efficiency as necessary.

### ***2.2.4 Project Element # 4 - Disposition of Treatment Residues***

After the radiolabeled products are trapped, they can be further processed and solidified in cement and disposed off-site, at the NRC-licensed low-level radioactive waste disposal facility in Barnwell, SC (as is currently done under the treatability exemption granted by PADEP). Additionally, OMP is currently working with various companies to develop and test technology to recover the radioactive component of the trapped effluent for reuse, in lieu of disposal via solidification or incineration. This option is further discussed in Section 3.2.1 and Section 5.1 below.

## ***3. How the Project Will Meet the Project XL Acceptance Criteria***

### ***3.1 Anticipated Superior Environmental Performance***

The use of OMP's high-temperature catalytic oxidation process, which treats the LLMW test samples as they are generated, potentially results in several environmentally superior benefits as compared to presently available commercial treatment and disposal alternatives involving incineration or land disposal:

- The radioactive component of OMP's LLMW is captured as a uniform, consistent waste stream and is amenable to recovery and reuse.
- Under OMP's proposal, all LLMW is handled on-site, in the NRC-regulated, controlled laboratory environment in which it is generated, thereby further reducing the potential for spills or releases during on-site and off-site handling, storage and transportation.

## **3.2 Additional Non-Environmental Benefits**

In addition to the anticipated elements of superior environmental performance mentioned above, the on-site treatment of LLMW utilizing high-temperature catalytic oxidation is also anticipated to result in other benefits as well. These benefits include: (1) opportunities to develop technologies to recycle/reuse tracer radionuclides and other technological advances, (2) cost savings, and (3) paperwork and labor reduction. Each of these benefits is detailed below. Additionally, the transferability of the benefits of this Project – facilitated by OMP's decision not to patent the technology and make it freely available to all interested parties – is discussed in Section 3.5 below.

### **3.2.1 Opportunities to Develop Radioactivity Recycling / Reuse and Other Technologies**

The principal advantage of excluding, from RCRA's definition of hazardous waste, the small volumes of LLMW generated and treated (using OMP's HTO process) within an NRC-licensed pharmaceutical research and development laboratory, is the potential for generating a uniform, non-RCRA hazardous waste stream of low-level radioactive waste that is amenable to recycling and reuse. This is an improvement over the alternative management (i.e. disposal) of air pollution control residues containing the radionuclides. Additionally, there has been interest from outside parties who would like to utilize and improve on the technology developed by OMP to facilitate the recycling of radioactivity (also see Section 3.5).

- An international company is interested in recovering tritium from the radioactive water generated by the catalytic oxidation process. This process would recycle the radionuclide tracer and eliminate its release into the environment. The technology to recover and reuse tritium is currently available and there is notable interest in developing the market utilizing this approach.
- A domestic company would like to manufacture a standard bench-top system, based on OMP's unit, that could be sold off-the-shelf to research institutions enabling them to perform on-site treatment in a laboratory setting. This would produce a uniform radioactive waste

stream that is receptive to recycling, the availability of which would allow for the further development of a market for radionuclide recycling.

- A TSDF currently licensed by the NRC and permitted under RCRA to treat LLMW is interested in scaling-up the catalytic oxidation process to create a viable, environmentally-sound, cost-effective, commercial treatment alternative for LLMW in which radioactivity could be recovered.

### **3.2.2 Cost Savings**

Currently, many research institutions do not undertake research that generates LLMW due to the limited disposal options and high disposal costs associated with these wastes. OMP's alternative environmental management strategy would result in a considerable cost savings opportunity for OMP, Johnson & Johnson, and other research and development (R&D) institutions which conduct this type of research. Current commercially available TSDF's charge up to \$40,000 per curie of activity to treat LLMW. Based on the survey of 100 domestic pharmaceutical companies, universities, commercial facilities and other organizations, conducted by the International Isotope Society in 1996, domestic institutions generate approximately 16,000 curies of tritium and carbon-14 LLMW annually. At an average disposal cost of \$30,000 per curie (which does not include costs for waste analysis and transportation), disposal of LLMW is costing domestic companies, conservatively, up to \$480 million per year. For OMP, disposal costs would range from \$250,000 to \$300,000 per year for LLMW if OMP were unable to use its HTO process. Company-wide, Johnson & Johnson believes these disposal costs may exceed \$1.5 million per year. These costs may be passed on to customers in higher costs for prescriptions and other pharmaceutical products.

### **3.2.3 Paperwork and Labor Reduction**

Facilities subject to the RCRA permitting requirements for the on-site treatment of hazardous wastes under 40 CFR Part 270 are subject to an extensive, time-consuming, permit application process and compliance program. While appropriate to commercial facilities which are in the business of treating large quantities of wastes from many different sources, the Parties to this Agreement believe that these requirements are not necessary with respect to OMP's bench scale HTO process, when it is undertaken within OMP's NRC-licensed laboratory and subject to the limits and conditions described herein. Allowing the regulatory flexibility to treat small volumes of LLMW on-site without a RCRA permit under these specified conditions (see Section 4 for further details) would relieve the associated paperwork and resource burden providing additional benefits to both the sponsor and regulatory agencies.

### **3.3 Stakeholder Involvement and Support**

OMP has mounted an extensive effort to measure and ascertain stakeholder involvement and support for this Project. OMP focused on a number of stakeholder groups, including the local community, Johnson & Johnson Spring House employees, State and Federal regulatory agencies, and local, state and national environmental groups. Support for the Project has been generally positive from all stakeholders to date. Copies of all correspondence from stakeholders and commenters, as well as summaries of public meetings, are included in the project Information Repository as set forth in Section 3.3.5.

#### **3.3.1 Regulatory Authorities**

OMP hosted a meeting on October 20, 1999 to explain its Project XL proposal to State and Federal regulatory agencies. The meeting included representatives from the EPA Headquarters, EPA Region III, PADEP, NRC, the Lawrence Berkeley National Laboratory, Johnson & Johnson Worldwide Environmental Affairs, Johnson & Johnson Safety & Industrial Hygiene, the R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical. The purpose of the meeting was to familiarize the agencies with OMP's proposal including the background, benefits and requested flexibility. EPA and PADEP have continued to communicate with each other regarding this project, including how to best carry out the intentions of the Parties as expressed in this Agreement.

#### **3.3.2 Local Community and Environmental Groups**

Stakeholder involvement from the local community and local environmental groups has been cultivated in many ways during the developmental stages of the Project. These methods include communicating through the news media, announcements at Township meetings, public meetings and direct contact of interested parties.

The local community has been involved in the Project through a variety of methods. OMP actively participates in two community environmental groups: The Lower Gwynedd Township (LGT) Industrial Compact (Compact) and the Community Advisory Council (CAC) sponsored by Rohm & Haas Corporation. The Compact includes members of the five major industries in Lower Gwynedd Township – Ortho-McNeil, Rohm & Haas, COGNIS (formerly Henkel Corporation), Siemens-Moore Process Automation Inc. (formerly Moore Products), and Aventis Crop Sciences (formerly Rhone-Poulenc, Inc.) – the LGT Supervisors, Township Manager and Fire Marshall and two township citizens. The Compact meets quarterly and provides a regular forum for open discussions about relevant information about the use of hazardous substances within LGT and other environmentally related issues. OMP is also a regular member of the CAC which has approximately 30 community residents who meet to discuss business issues, including

environmental issues, with Rohm & Haas and OMP on a quarterly basis. During the development stages, OMP has provided continuous updates on this Project to the Compact and CAC and solicited comments, and plans to continue updating the community groups during the implementation of the Project.

At a LGT supervisor meeting on February 16, 2000, OMP announced the acceptance of the Project by the EPA into its Project XL Program and invited the community to attend a public meeting to be held at the OMP facility. A newspaper article announcing the public meeting was published in *The Reporter* on February 16, 2000. OMP also personally invited all the members of the LGT Compact and the CAC to attend the public meeting as well as the Executive Director of the local Wissahickon Valley Watershed Association. OMP hosted the public meeting on the Project on February 28, 2000. *The Ambler Gazette* published an article about the meeting and Project on March 1, 2000 (See Appendix D for copies of the articles).

On July 18, 2000, OMP hosted a stakeholder meeting at its Spring House facility. The meeting was attended by representatives from EPA, PADEP, OMP, and Johnson & Johnson and focused specifically on addressing concerns raised by the Sierra Club, which was also represented at the meeting. The objectives of the meeting were to brief the Sierra Club representative about the EPA Project XL Program and provide the history of the OMP XL project, to discuss the catalytic oxidation treatment process with OMP scientists, to explain the regulatory oversight for OMP's XL project and to address any specific concerns raised by the Sierra Club with respect to OMP's project. The meeting also included a site tour including the radiosynthesis laboratory suite, which houses the high-temperature catalytic oxidation unit. In addition, a draft version of this FPA was reviewed by all participants. After the meeting and a more thorough review of the draft FPA, the Sierra Club submitted extensive comments on the FPA, which have been addressed in this version of the FPA. A list of stakeholders who were invited to the meeting is available in the project Information Repository (see Section 1.5) along with the agenda and the attendance sheet.

OMP will hold periodic public meetings with the local community to provide updates and information on the Project, and to address any concerns that may arise.

### **3.3.3 National Environmental Groups**

OMP has worked with the EPA and a third party consultant to notify and communicate with national environmental groups, and other interested parties about the Project. Appendix H lists all of the environmental, industry and other groups and associations that OMP has informed about this proposed Project. The project Information Repository includes comments received (including comments on prior drafts of this FPA).



### **3.3.4 Other Interested Parties**

The success of HTO in the treatment of mixed wastes at OMP has generated great interest among many parties including government agencies, the National Tritium Labeling Facility, the National Institutes of Health, domestic and international pharmaceutical companies, commercial manufacturers, raw material suppliers and mixed waste treatment facilities.

### **3.3.5 Project Information Repository**

A collection of project documents has been established in the Lower Gwynedd Township building, located at 1130 North Bethlehem Pike, Spring House, Pennsylvania 19477. This information repository contains records of all stakeholder meetings, identification of the stakeholders, relevant materials and minutes. Those on the project mailing list, including all stakeholders, participants in the FPA development process, and any members of the general public who have expressed interest in the project, have had copies of all minutes and other materials from the meetings, including the drafts of the FPA, made available to them. The stakeholders and interested parties on the project mailing list can be found in Appendix H. EPA has established a website located at [www.epa.gov/Projectxl](http://www.epa.gov/Projectxl) that also contains project documents.

### **3.3.6 Annual Stakeholder Meetings/Updates**

Stakeholder meetings shall be held annually, on or within two months of the annual anniversary of the signing of the FPA.

## **3.4 Innovative Approach and Multi-Media Pollution Prevention**

OMP's proposal - to treat small quantities of LLMW generated by R&D activities utilizing a bench-top high-temperature catalytic oxidation process to destroy the organic component of the "waste" while capturing the radioactive component in a highly controlled laboratory environment - represents an innovative, alternative approach to currently available methods for the management and treatment of LLMW. As previously discussed, the current commercially available method requires the off-site transportation and treatment of LLMW via incineration at a permitted TSD facility. OMP's proposal would capture the radioactivity from this waste stream and allow for the potential recovery and reuse of the radioisotope (see Section 3.2.1 and Section 5.1 for more details on this potential recycling alternative).

OMP recognizes that pollution prevention is the cornerstone of a proactive waste management program. While this Project focuses specifically on the "end-of-pipe" treatment of LLMW unavoidably generated during R&D operations due to current FDA protocol, OMP has made a concerted effort at minimizing all other R&D wastes at the source (i.e. pollution prevention) through the implementation of a comprehensive Waste Minimization



Program (WMP). This WMP, which was implemented in January 1998, uses a performance-based approach to encourage the implementation of new and innovative ideas to minimize all R&D wastes at their point of generation. The WMP targets hazardous and radioactive wastes as well as air emissions, wastewater discharges and biohazardous and non-hazardous wastes. The goal of the program is to have each R&D Department (13 in all) submit three waste minimization ideas per year and to implement at least one new waste minimization practice per year. The WMP has been endorsed by upper management and has been very successful. To date, 26 waste minimization practices have been implemented resulting in the following benefits:

#### **Waste Minimization**

Hazardous Waste – reduced by 34,605 pounds  
Biohazardous Waste – reduced by 3,905 pounds  
Radioactive Waste – reduced by 275 pounds  
Non-Hazardous Waste – reduced by 93,530 pounds  
Wastewater – reduced by 700,000 gallons

#### **Cost Savings**

Disposal Costs	= \$ 42,572
Material Costs	= \$ 62,433
Labor Costs	= <u>\$ 20,200</u>
Total Savings:	\$125,205

#### **Miscellaneous Benefits**

Recycling – increased by 6,105 pounds  
Labor – reduced by 2,016 man-hours

The OMP Waste Minimization Program was recognized by the Commonwealth of Pennsylvania with the Governor's Award for Environmental Excellence in 1998.

### **3.5 Transferability of the Approach to Other Entities or Sectors**

EPA has recognized that nationally, the capacity for the treatment and disposal of certain LLMW is not available and that it is appropriate to provide safe and legal alternatives for the disposal of LLMW.

Ortho-McNeil has found that the limited availability of mixed waste disposal facilities, high disposal costs, the lack of adequate storage facilities, and current regulatory restrictions on treatment options and accumulation times have severely restricted most research activities that generate mixed wastes. This has caused a disadvantage for domestic pharmaceutical research institutions, which must utilize radioactive materials if they are to compete in the highly competitive commercial arena. High disposal costs limit research activities that generate mixed wastes and have effectively locked out small research institutions and universities from participating in this research.

The HTCO technology developed by OMP is transferable to any organization that generates or treats mixed wastes. This includes pharmaceutical companies, research institutions, and colleges and universities, among others. OMP believes that this process is an environmentally superior method for the management of LLMW, and has decided not to patent the technology and has made it available to all interested parties.

In addition, OMP has dedicated its own time and resources to help interested parties implement this technology. As of today, OMP has worked with three companies or organizations who are using this technology: 1) the Research Triangle Institute in North Carolina, 2) the Lawrence Berkeley National Laboratory in California and 3) Ontario Power Technologies, a technology company in Ontario, Canada interested in commercializing the HTCO process. The Research Triangle Institute and the Lawrence Berkeley National Lab, like OMP, are both operating bench-scale systems under a State Treatability Study exemption. Ontario Power Technologies has scaled-up the system for commercial use. OMP has hosted and provided demonstrations to almost 100 companies, organizations and individuals who have shown interest in utilizing this technology. These outreach efforts are discussed further in Appendix G.

### **3.6 Feasibility of the Project**

Ortho-McNeil has operated the high-temperature catalytic oxidation process since January 1996 under a Treatability Study exemption approved by the PADEP. To date, 27 test samples with a total volume of 20,404 mL and a total activity of 1,920.373 mCi have been tested for process effectiveness under the Treatability Study. Over 2400 hours of development and operating experience by OMP, and other companies at several sites, has shown that the process effectively destroys a wide variety of materials in a safe operation. During the Treatability Study, the catalytic oxidation process has been run under a wide range of operating conditions, with a multitude of organic materials, to achieve optimal efficiency. See Appendix B for a list of hazardous organic components and their corresponding destruction removal efficiencies (DRE).

OMP management fully supports this Project and will ensure that sufficient resources are allocated to implement it.

### **3.7 Monitoring, Reporting, Accountability, and Evaluation Methods**

#### **3.7.1 Monitoring**

##### **3.7.1.1 Organic Concentration in Effluent and Destruction Removal Efficiency**

The organic concentration in the effluent from the process has been monitored utilizing gas chromatography (GC) with a detection limit of 50 ppb. GC analysis has proven that the process has been extremely effective in treating a broad range of organic solvents and has routinely achieved DRE of 99.999% to 99.99999%. OMP will continue to monitor the process to ensure that such DREs are maintained. This monitoring includes the continuous monitoring of carbon monoxide (CO) while the process is running. The oxidation process is complete when no CO is detected, indicating that organics present in the sample have been destroyed to levels less than 0.1 parts per million. GC analysis will be performed on any new organic compound not previously processed. In addition, Appendix B contains a detailed description of the Experimental Conditions under which the samples from the effluent stream are collected and analyzed.

#### **3.7.1.2 Radioactivity in Effluent**

Liquid scintillation analysis and radioactive mass balances have been used to measure radioactivity in the effluent from the process and has demonstrated that the catalytic oxidation process is a closed-loop system to  $99 \pm 1\%$ .

#### **3.7.1.3 Radioactivity in Air Emissions**

OMP is licensed by the NRC to use radioactive materials in its research laboratories pursuant to a "Type A Broad Scope" license for research and development. The radioactive materials license states that "concentrations in effluent air shall be within the limits specified in 10 CFR 20." The NRC effluent limits in 10 CFR 20 are  $2.00\text{E}-8$   $\mu\text{Ci/mL}$  for tritium and  $6.00\text{E}-8$   $\mu\text{Ci/mL}$  for carbon-14. The catalytic oxidation unit is housed in a laboratory fume hood within the radiosynthesis lab suite. All seven (7) fume hoods in the lab suite are connected to a dedicated stack for air emissions. No other pharmaceutical research operations, or other processes performed at the facility, are tied into this system. Air emissions monitoring for radioactivity is performed whenever the process is operating. The monitoring is performed on the consolidated, non-turbulent air stream within the ventilation system after the juncture of the seven hoods and prior to emissions into the atmosphere via the dedicated stack. During calendar year 1999, air emissions monitoring revealed an annual average effluent concentration of  $3.55\text{E}-12$   $\mu\text{Ci/mL}$  for tritium and  $3.03\text{E}-11$   $\mu\text{Ci/mL}$  for carbon-14. As can be seen from these results, the 1999 air concentrations were less than 0.05% of the limits specified by the NRC in 10 CFR Part 20 for allowable concentrations in effluent air. Air emissions monitoring results are available in the Project Information Repository identified in Section 1.5, above.

#### **3.7.2 Reporting**

Under the treatability study exemption, OMP is required to submit annual

reports to the Pennsylvania Department of Environmental Protection. The annual report contains the information required by 25 PA Code Section 261.4(f)(9). This information is as follows:

- I] Facility Information
  - a. Company
  - b. EPA ID No.
  - c. Point of Contact
- II] Summary of Previous Year's Treatability Studies
  - a. Name, Address and EPA ID Number of Generator of Samples
  - b. Types, by Process, of Treatability Studies Conducted
  - c. Names, Address and EPA ID Number of Persons for Whom Studies Have Been Conducted
  - d. Total Quantity of Waste in Storage Each Day
  - e. Quantity and Types of Waste Subjected to Treatability Studies
  - f. Date each Treatability Study was Conducted
  - g. Final Disposition of Unused Samples/Residues from Each Treatability Study
- III] Current Year's Treatability Studies Forecast
  - a. Estimate of Number of Studies to be Conducted
  - b. Amount of Waste Expected to be used in Treatability Studies

See Appendix E for the Calendar Year 1999 Annual Treatability Report submitted by Ortho-McNeil to the PADEP on March 14, 2000. The annual reports from 1996 to date are available in the Project Information Repository identified in Section 1.5.

As part of this project, OMP will continue to prepare and submit reports containing this information to PADEP and EPA biannually (twice a year), beginning six months following the effective date of this FPA.

Additionally, OMP will include the following additional information in each biannual report:

- a. The calculated DRE for organic compounds in each batch, including the basis for this determination.
- b. The calculated recovery rate of the radioactivity, including the basis for this determination.

### **3.7.3 Accountability**

OMP assumes all accountability for monitoring, recordkeeping, reporting and evaluating the progress of the Project. OMP will continue to monitor the process effluent streams as described Section 3.7.1. In addition, OMP will continue to keep records and submit reports to the PA DEP and the EPA as discussed in Section 3.7.2.

#### **3.7.4 Evaluation Methods**

OMP will continue to monitor and evaluate the efficiency of the catalytic oxidation process as discussed in Section 3.7.1. As part of this project, OMP will submit this data, as well as other information relevant to the success of the Project, in a biannual report to EPA and PADEP.

#### **3.8 Avoidance of Shifting the Risk of Burden**

The implementation of this Project will not result in a shifting of risk from one environmental media to another. OMP will continue to comply with all applicable State and Federal requirements (other than those associated with TSDF permitting) during the implementation of the Project. These requirements include PADEP and EPA regulations concerning the management of hazardous wastes and NRC regulations for handling radioactive materials in accordance with OMP's "Type A Broad Scope" license for research and development.

OMP has reviewed Executive Order 12898 on Environmental Justice and has concluded that the Project will not result in any unjust or disproportionate environmental impacts.

### **4. *Regulatory Framework: Background; Description of the Requested Flexibility; and Anticipated Implementing Mechanism***

#### **4.1 Background: Regulatory Status of Mixed Waste in Pennsylvania under the AEA and RCRA**

Mixed waste, including LLMW such as OMP's, comprises both radioactive and hazardous wastes, regulated under two federal statutes. In Pennsylvania, radioactive wastes are regulated by the Nuclear Regulatory Commission (NRC) under the Atomic Energy Act (AEA), 42 U.S.C. §§ 2011-2296. The AEA regulates three types of materials associated with radiation hazards: "source, special nuclear, and byproduct material." *Id.* at § 2021. Hazardous wastes are regulated by EPA and/or Pennsylvania under the Resource, Conservation, and Recovery Act (RCRA), 42 U.S.C. § 6901, *et seq.*, as well as by Pennsylvania under applicable state laws, including the Solid Waste Management Act (SWMA), 35 P.S. §§ 6018.101 - 6020.1304. Facilities handling mixed waste generally must comply with both AEA and RCRA statutes and regulations, whose requirements are generally consistent and compatible. However, Congress did specifically exclude "source," "special nuclear," and "byproduct material" from RCRA's definition of solid waste (and thus hazardous waste and the Subtitle C program), to avoid overlap with the AEA. See 42 U.S.C. § 6903(27). Moreover, Section 1006(a) of RCRA, 42 U.S.C. 6905(a), provides that the AEA shall take precedence in the event

provisions of requirements of the two acts are found to be inconsistent. The AEA thus retains exclusive authority over radioactive waste, while RCRA regulates nonradioactive waste.

Initially it was unclear whether "byproduct material" under the AEA included the hazardous waste portion of mixed waste in which case it might be excluded from the definition of solid waste" under 42 U.S.C. § 6903(27). In a July 3, 1986 Federal Register notice (51 FR 24504), EPA announced its determination that the hazardous waste portion of mixed waste is not byproduct material and therefore is subject to dual AEA/RCRA regulation (with which determination DOE subsequently agreed, see 10 C.F.R. § 962.3). In this same notice EPA also announced that "States that already have authorized [RCRA] programs must revise their programs (if necessary) and must apply for authorization for hazardous components of radioactive mixed waste."

Pennsylvania received authorization to implement the RCRA base program on January 30, 1986, prior to EPA's July 3, 1986 Federal Register notice.<sup>1</sup> Therefore in Pennsylvania at present, mixed wastes are not considered RCRA hazardous wastes, and thus are not subject to RCRA.<sup>2</sup> Pennsylvania does exercise independent authority over mixed waste under its Solid Waste Management Act, 35 P.S. §§ 6018.101 - 6020.1304 (SWMA), and it has been under this authority that OMP has been processing its LLMW in its catalytic oxidation unit pursuant to the SWMA's provisions governing treatability studies.

This XL project was undertaken and developed by EPA, PADEP, and OMP under the assumption that Pennsylvania will receive authorization for mixed wastes prior to implementation of required regulatory flexibility (discussed further in Section 4.2).

## **4.2 Requested Flexibility -**

### **4.2.1 Background and Basis for Requested Flexibility**

RCRA generally requires that a facility such as OMP's obtain a RCRA permit in order to treat on-site materials designated as "hazardous

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<sup>1</sup> Section 3006(b) of RCRA provides that States may apply to EPA for authorization to administer and enforce a hazardous waste program pursuant to Subtitle C of RCRA. Authorized State programs are carried out in lieu of the Federal program. Pennsylvania received its initial authorization to implement provisions of RCRA effective January 30, 1986 (51 Fed. Reg. 1791, January 15, 1986).

<sup>2</sup> Pennsylvania has prepared a revised RCRA authorization package, incorporating provisions of SWMA and other Commonwealth statutes and specifically requesting authorization to regulate mixed waste, which it has submitted to EPA. As required by RCRA, the Commonwealth's Statement of its Attorney General notes that the Commonwealth adopts EPA's determination that the hazardous waste portion of mixed waste is not byproduct materials and is subject to RCRA.

wastes," subject to certain exceptions and exemptions. (See 40 C.F.R. § 270.13 and § 270.14 and applicable sections in 40 C.F.R. § 270.15 through § 270.29). Assuming OMP's LLMW is a RCRA hazardous waste, its HTOC process meets RCRA's definition of "treatment" (which typically triggers a requirement to obtain a RCRA permit) because the oxidation destroys the organic components of the samples.<sup>3</sup>

Notwithstanding its July 1986 **Federal Register** notice in which it announced its determination that the hazardous waste portion of mixed waste is subject to dual AEA/RCRA regulation, EPA has recognized the potential that RCRA and AEA requirements can pose unnecessarily duplicative regulatory requirements. On November 19, 1999, after reviewing comments received on a March 1, 1999 Advanced Notice of Proposed Rulemaking, EPA issued a Proposed Rule for the Storage, Treatment, Transportation, and Disposal of Mixed Waste under 40 CFR Part 266. In the Proposed Rule, the EPA would allow the on-site treatment of LLMW (and on-site storage of LLMW), without a RCRA treatment permit, where the LLMW is physically or chemically treated in a tank or container in accordance with the generator's NRC license requirements. However, EPA determined that, based on information then available, certain forms of treatment would not be included within the proposed exemption. OMP's HTOC process would be included in those processes not eligible for the proposed exemption. Therefore, the November 19, 1999 proposed Rule, even if adopted, would not allow OMP to utilize the high-temperature catalytic oxidation process without a RCRA TSDF permit.

OMP does not wish to apply for a RCRA TSDF permit for its Spring House facility. OMP states that it is a healthcare company and does not wish to be in the business of commercial hazardous waste treatment. OMP states that it does not and will not ever accept LLMW from off-site generators for treatment at its facility. In addition, OMP believes that the current regulations, which require a RCRA TSDF permit to treat hazardous wastes, generally are not necessary for the type of treatment encompassed in its HTOC processing of laboratory-scale waste at its Spring House facility.

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<sup>3</sup> OMP did consider whether its NRC-licensed laboratory met the definition of a "totally-enclosed treatment facility" as defined in 40 CFR § 260.10, in which case a TSDF permit would not be required under 40 CFR § 264.1(g)(5). OMP determined that it did not qualify for this exemption because its HTOC unit is not "directly connected to an industrial production process," as required by 40 CFR § 260.10.

Moreover, even if OMP had qualified for an exemption from the requirement that it obtain a TSDF permit under 40 CFR § 264.1(g)(5), the radioactive residue would still be subject to RCRA's "derived from" rule [40 CFR § 261.3(c)(2)(i)], under which any residues from the treatment of a listed hazardous waste are deemed to remain a hazardous waste. OMP anticipates that some of the LLMW it will process in its HTOC process will be listed hazardous waste.



EPA believes that, while RCRA's permit regulations would otherwise apply to OMP's HTCO process, the goals of protection of public health, welfare and the environment which are served by RCRA's TSDF permitting process are met at OMP's facility by the terms and conditions of OMP's NRC license (including in particular the very small quantities of LLMW involved and the controlled nature of the HTCO process), particularly when combined with the other terms and conditions of the regulatory relief which EPA and PADEP intend to provide under this Agreement (e.g., requirements imposed under PADEP's treatability study). The Parties to this FPA will negotiate other specific conditions as necessary to ensure protection of human health and the environment, which will be contained in the site-specific rule needed to implement the XL project.

#### **4.2.2 Requested Flexibility**

OMP is requesting that -

- (1) it be allowed to treat small volumes of LLMW on-site in its HTCO process without a RCRA TSDF permit, and
- (2) the radioactive residue from its HTCO process not be considered a hazardous waste.<sup>4</sup>

#### **4.2.3 Additional Flexibility**

The parties to the Agreement do not anticipate any need to provide flexibility from any additional Federal and/or State requirements. If the parties agree that additional flexibility is necessary and appropriate, the flexibility may be added to this Project and will be subject to public notice and comment, as appropriate.

### **4.3 Legal Implementing Mechanisms**

#### **4.3.1 Federal**

EPA believes that the most appropriate way to provide the requested regulatory flexibility is to add OMP's LLMW to the list of solid wastes which are excluded from the definition of hazardous waste under 40 CFR.

§ 261.4(b).<sup>5</sup> 40 CFR § 261.4(b) includes a number of solid wastes which would otherwise qualify as RCRA hazardous wastes, but which EPA has

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<sup>4</sup> Regardless of whether OMP is required to obtain a RCRA TSDF permit to process LLMW with its HTCO process, RCRA's "derived from" rule [40 CFR § 261.3(c)(2)(i)] provides that any residues from the treatment of a listed hazardous waste are deemed to remain a hazardous waste, subject to RCRA's manifesting requirements. OMP anticipates that some of the LLMW it will process in its HTCO will include listed hazardous waste.

<sup>5</sup> As discussed in Section 4.1 above, OMP's LLMW is not at present a RCRA hazardous waste in Pennsylvania. However, the parties anticipate that Pennsylvania's proposed revised base RCRA authorization program, under which OMP's LLMW will become a RCRA hazardous waste, will be in place by the time necessary regulatory changes are implemented.



determined do not require regulation as such because of the limited nature of the risks they pose, or because they are adequately regulated under another environmental program. EPA expects to propose a site-specific exclusion for OMP's LLMW, subject to several conditions, such as:

- The exclusion would apply only to OMP's LLMW which is created, and processed, within its NRC-licensed Spring House laboratory, in accordance with its NRC license and its existing PADEP treatability study conditions.
- OMP would not be permitted to process more than 50 liters of LLMW per year.
- OMP must monitor the Destruction Removal Efficiency for the hazardous organic component of the LLMW.
- OMP must monitor the capture efficiency for the radioactive component of the LLMW.
- OMP must report the data gathered to EPA and PADEP biannually

Excluding OMP's LLMW from RCRA's definition of hazardous waste would have the effect of removing RCRA jurisdiction over OMP's HTO processing of LLMW within OMP's NRC-licensed laboratory. NRC regulatory controls and oversight would continue for the low-level radioactive samples and treatment products that would remain from the process, and the residuals to be managed as a low-level radioactive waste.

#### **4.3.2 Pennsylvania**

Pennsylvania's hazardous waste regulations are structured such that the 40 CFR § 261.4 exclusions, as well as the bulk of the Title 40 federal hazardous waste regulations, are incorporated by reference into Title 25 of Pennsylvania's rules and regulations. The specific section of Pennsylvania's regulations that incorporates the 40 CFR § 261.4 exclusions is 25 Pa. Code § 261a.1. As provided for at 25 Pa. Code § 260a.3(e), the incorporation by reference includes any subsequent modifications and additions to the incorporated portions of the Code of Federal Regulations (CFR). Thus, EPA's addition of OMP's LLMW to the list of solid wastes which are excluded from the definition of hazardous wastes under 40 CFR § 261.4(b) would similarly exclude it from Pennsylvania's definition of hazardous waste, and OMP would not be required to obtain a hazardous waste permit from PADEP.

Since the OMP exclusion would be promulgated as an exclusion from classification as hazardous waste at 40 CFR § 261.4(b), the material would still be regulated as residual waste under Title 25, Article IX of

Pennsylvania's rules and regulations. PADEP anticipates granting a permit by rule under 25 Pa. Code § 270a.60, because OMP's catalytic oxidation process could be deemed to have a residual waste processing permit (captive processing facility permit-by-rule) if the conditions of 25 Pa. Code § 287.102(b) are met.

If the radioactivity-containing residuals from OMP's HTCO process qualify as "residual waste" under the SWMA, PADEP anticipates issuing a permit by rule under 25 Pa. Code § 270a.60.

## **5.0 Discussion of Intentions and Commitments for Implementing the Project**

### **5.1 Ortho-McNeil's Intentions and Commitments**

#### **5.1.1 Intentions**

OMP's ultimate goal is to make high-temperature catalytic oxidation with the capture, recovery and reuse of the radionuclide tracer component the worldwide standard for the treatment of research-generated LLMW. OMP is fully committed to accomplishing this goal.

Pursuing this XL Project is the first step in achieving this objective. OMP intends to continue to study various LLMW streams to further improve the efficiency of the catalytic oxidation system and to better define the parameters and capabilities of the system.

#### **5.1.2 Commitments**

In conducting this Project, OMP commits to comply fully with all applicable laws and regulations (including, without limitation, all applicable air emission concentration limits as required under the federal Clean Air Act and as specified in OMP's NRC license which are  $2.00\text{E-}8$   $\mu\text{Ci/mL}$  for tritium and  $6.00\text{E-}8$   $\mu\text{Ci/mL}$  for carbon-14), permit conditions, and legal implementing mechanisms and all other elements set forth in this Agreement.

Specifically, OMP commits to the following conditions and limitations on the scope of this project, and recognizes that EPA and PADEP intends to include them as enforceable conditions in the site-specific regulatory mechanism(s) which the agencies intend to use to carry out this project:

1. OMP agrees to process only LLMW generated within its NRC-licensed Spring House facility, and only up to the volume limits set forth in the PADEP Treatability Study, i.e. 50 liters per year, to meet the reporting requirements set forth in Section 3.7.2.

2. Monitor and report, biannually, Destruction Removal Efficiencies for all organic components of the LLMW subject to treatment.
3. Monitor and report, biannually, capture efficiencies for the radioactive component of the LLMW subject to treatment.

In addition, OMP commits (but without the weight of enforceable conditions) to continue to work with other companies, other organizations, and research institutions to:

1. Develop a standard, bench-scale, off-the-shelf treatment unit, based on its HTCO technology, to be made available to companies and institutions that generate R&D quantities of LLMW.
2. Further develop the technology and market for recycling and reuse of the radioactive component of LLMW. In support of this goal, OMP will prepare (and submit to EPA for review and comment) a proposed plan summarizing how it expects to accomplish this goal.

## **5.2 EPA's and PADEP's Intentions and Commitments**

The EPA intends to propose and issue (subject to applicable procedures and review of public comments) a site-specific rule, amending 40 CFR Part 261.4, which applies to the OMP Spring House facility. The site-specific rule will also allow for withdrawal or termination and a post-Project compliance period consistent with Sections 10 and 11 of this Agreement, and will allow for the transfer procedures included in Section 8. The standards and reporting requirements set forth in Section 3.7 will be implemented through the site-specific rule.

The Pennsylvania Department of Environmental Protection intends to propose and issue (subject to applicable procedures and review of public comments) a permit-by-rule as necessary under 25 Pa. Code § 270a.60.

## **5.3 Project XL Performance Targets**

Ortho-McNeil intends to achieve the following performance targets during the implementation of the Project:

1. Achieve Destruction Removal Efficiencies of 99.999% or higher for all organic components of the LLMW subject to treatment.
2. Achieve capture efficiencies of 99% or greater for the radioactive component of the LLMW subject to treatment.

#### **5.4 Proposed Schedule and Milestones**

OMP will continue to operate the catalytic oxidation process under its PADEP treatability study exemption until this Final Project Agreement is signed and its terms implemented through the appropriate legal implementing mechanism(s).

#### **5.5 Project Tracking, Reporting and Evaluation**

As set forth in this Agreement, the Project is expected to achieve superior environmental performance to that which would otherwise be achieved through traditional regulatory compliance. To evaluate the performance and results of the Project, OMP must prepare biannual evaluation reports to be submitted to the EPA and PADEP, which will include the annual report elements outlined in Section 3.7.2. The biannual evaluation will include a summary of the efforts made by OMP with respect to the intentions and commitments in Section 5.1 and a summary of the performance targets in Section 5.3 above.

The EPA, PADEP and OMP will re-evaluate the regulatory flexibility and legal implementation mechanisms of the Project in the event that the EPA or PADEP issues any proposed or new rule or regulation, which has material relevance to the project.

In addition, the Parties will evaluate the status and overall success of the Project as discussed in Section 5.7 below. OMP will prepare a draft evaluation report, which it will provide to the other stakeholders no later than ninety (90) days prior to the scheduled termination of the Project, which will include:

1. An analysis of the superior environmental performance achieved by the Project as set forth in this Agreement,
2. A comparison of the environmental benefits originally anticipated to result from OMP's commitments under the Project and the benefits actually achieved by the Project,
3. A review of any new statutory or regulatory requirements applicable to the Project,
4. An analysis as to whether the continuation of the Project is warranted based on continued or future anticipated superior environmental performance, and
5. If applicable, a proposal to continue the Project including any modifications or enhancements to the Project to continue achieving superior environmental performance.

## **5.6 Periodic Review by the Parties to the Agreement**

The Parties will hold periodic performance review conferences to assess their progress in implementing the Project. Unless they agree otherwise, the date for these conferences will be concurrent with annual Stakeholder Meetings. No later than thirty (30) days following a periodic performance review conference, OMP will provide a summary of the minutes of the conference to all Direct Stakeholders and to the Project Information Repository. Any additional comments of participating Stakeholders will be reported to the EPA.

## **5.7 Duration of the Project**

This Agreement will remain in effect for five (5) years, unless the Project ends at an earlier date, as provided in Section 7 (Amendments or Modifications to the Agreement), or Section 8 (Transfer of Project Benefits and Responsibilities to a New Owner). The implementing mechanism(s) will contain "sunset" provisions ending authorization for the Project five (5) years after the effective date of the site-specific rule or permit. The implementing mechanism(s) will also address withdrawal or termination conditions and procedures as described in Section 10. This Project will not extend past the agreed upon date, and OMP will comply with all applicable requirements following this date, unless all parties agree to an amendment to the Project term.

## **6. *Legal Basis for the Project***

### **6.1 Authority to Enter into the Agreement**

By signing this agreement, the EPA, the Commonwealth of Pennsylvania, and OMP acknowledge and agree that they have the respective authorities, discretion, and resources to enter into this Agreement and to implement all applicable provisions of this Project, as described in this Agreement.

### **6.2 Legal Effect of the Agreement**

This Agreement states the intentions of the Parties with respect to OMP's XL Project. The Parties have stated their intentions seriously and in good faith, and expect to carry out their stated intentions.

This Agreement in itself does not create or modify legal rights or obligations, is not a contract or a regulatory action, such as a permit or a rule, and is not legally binding or enforceable against any Party. Rather, it expresses the plans and intentions of the Parties without making those plans and intentions binding requirements. This applies to the provisions of this Agreement that

concern procedural as well as substantive matters. For example, the Agreement establishes procedures that the Parties intend to follow with respect to dispute resolution and terminations (see Sections 9 and 10). However, while the Parties fully intend to adhere to these procedures, they are not legally obligated to do so.

The EPA intends to propose for public comment the site-specific rule and/or permit needed to implement this Project. Any rules, permit modifications or legal mechanisms that implement this Project will be effective and enforceable as provided under applicable law.

This Agreement is not a "final agency action" by the EPA, because it does not create or modify legal rights or obligations and is not legally enforceable. This Agreement itself is not subject to judicial review or enforcement. Nothing any Party does or does not do that deviates from the provisions of this Agreement, or that is alleged to deviate from the provisions, of this Agreement, can serve as the sole basis for any claim for damages, compensation or relief against any Party.

### **6.3 Other Laws or Regulations that may Apply**

Except as provided in the legal implementing mechanism(s) for this Project, the Parties do not intend that this project will modify any other existing or future laws or regulations.

### **6.4 Retention of Rights to Other Legal Remedies**

Except as expressly provided in the legal implementing mechanism(s) described in Section 4.2, nothing in this Agreement affects or limits OMP's, EPA's, the Commonwealth of Pennsylvania's, or any other signatory's legal rights. These rights may include legal, equitable, civil, criminal or administrative claims or other relief regarding the enforcement of present or future applicable federal and state laws, rules, regulations or permits with respect to the facility.

Although OMP does not intend to challenge agency actions implementing the Project (including any rule amendments or adoptions, permit actions, or other actions) that are consistent with this Agreement, OMP reserves any rights it may have to appeal or otherwise challenge any EPA or PADEP action to implement the Project. With regard to the legal implementing mechanism(s), nothing in this Agreement is intended to limit OMP's right to an administrative or judicial appeal or review of the legal mechanism(s), in accordance with the applicable procedures for such review.

## **7. *Amendments or Modifications to the Agreement***

This Project is an experiment designed to test new approaches to environmental protection and there is a degree of uncertainty regarding the environmental benefits and costs associated with activities to be undertaken in this Project. Therefore, it may be appropriate and necessary to amend this Agreement at some point during the duration of the Project.

This Final Project Agreement may be amended by mutual agreement of all Parties at any time during the duration of the Project. The parties recognize that amendments to this Agreement may also necessitate modification of legal implementation mechanism or may require development of new implementation mechanism(s). If the Agreement is amended, the EPA and OMP expect to work together with other regulatory bodies and stakeholders to identify and pursue any necessary modifications or additions to the implementation mechanisms in accordance with applicable procedures. If the Parties agree to make a substantial amendment to this Agreement, the general public will receive notice of the amendment and be given an opportunity to participate in the process, as appropriate.

In determining whether to amend the Agreement, the Parties will evaluate whether the proposed amendment meets Project XL acceptance criteria and any other relevant considerations agreed on by the Parties. All Parties to the Agreement will meet within ninety (90) days following submission of any amendment proposal (or within a shorter or longer period if all Parties agree) to discuss evaluation of the proposed amendment. If all Parties support the proposed amendments, the Parties will (after appropriate stakeholder involvement) amend the Agreement.

## **8. *Transfer of Project Benefits and Responsibilities to a New Owner***

The Parties expect the implementing mechanisms will allow for a transfer of OMP's benefits and responsibilities under the Project to any future owner or operator upon request of OMP and the new owner or operator, provided that the following conditions are met:

- A. OMP will provide written notice of any such proposed transfer to EPA and PADEP at least ninety (90) days before the effective date of the transfer. The notice is expected to include identification of the proposed new owner or operator, a description of its financial and technical capability to assume the obligations associated with the Project, and a statement of the new owner or operator's intention to take over the responsibilities in the XL Project of the existing owner or operator.

- B. Within forty-five (45) days of receipt of the written notice, the Parties expect EPA and PADEP, in consultation with all stakeholders, will determine whether: 1) the new owner or operator has demonstrated adequate capability to meet EPA's requirements for carrying out the XL Project; 2) is willing to take over the responsibilities in the XL Project of the existing owner or operator; and 3) is otherwise an appropriate Project XL partner. Other relevant factors, including the new owner or operator's record of compliance with Federal, State and local environmental requirements, may be considered as well.

It will be necessary to modify the Agreement to reflect the new owner and it may also be necessary for EPA and PADEP to amend the appropriate rules, permits, or other implementing mechanisms (subject to applicable public notice and comment) to transfer the legal rights and obligations of OMP under this Project to the proposed new owner or operator.

## **9. *Process for Resolving Disputes***

Any dispute, which arises under, or with respect to, this Agreement will be subject to informal negotiations between the Parties to the Agreement. The period of informal negotiations will not exceed twenty (20) calendar days from the time the dispute is first documented, unless that period is extended by a written agreement of the Parties to the dispute. The dispute will be considered documented when one Party sends a written Notice of Dispute to the other Parties.

If the Parties cannot resolve a dispute through informal negotiations, the Parties may invoke non-binding mediation by describing the dispute with a proposal for resolution in a letter to the Regional Administrator for EPA Region III. The Regional Administrator will serve as the non-binding mediator and may request an informal mediation meeting to attempt to resolve the dispute. He or she will then issue a written opinion that will be non-binding and does not constitute a final EPA action. If this effort is not successful, the Parties still have the option to terminate or withdraw from the Agreement, as set forth in Section 10 below.

## **10. *Withdrawal From or Termination of the Agreement***

### **10.1 *Expectations***

Although this Agreement is not legally binding and any Party may withdraw from the Agreement at any time, it is the desire of the Parties that it should remain in effect through the expected duration of five (5) years, and be implemented as fully as possible unless one of the conditions below occurs:



1. Failure by any Party to (a) comply with the provisions of the enforceable implementing mechanisms (i.e., conditions) for this Project, or (b) act in accordance with the provisions of this Agreement. The Assessment of the failure will take nature and duration into account.
2. Failure of any Party to disclose material facts during development of the Agreement.
3. Failure of the Project to provide superior environmental performance consistent with the provisions of this Agreement.
4. Enactment or promulgation of any environmental, health or safety law or regulation after execution of the Agreement, which renders the Project legally, technically or economically impracticable.
5. Decision by an agency to reject the transfer of the Project to a new owner or operator of the facility.

In addition, EPA and PADEP do not intend to withdraw from the Agreement if OMP does not act in accordance with this Agreement or its implementation mechanisms, unless the actions constitute a "substantial failure" to act consistently with intentions expressed in this Agreement and its implementing mechanisms. The decision to withdraw will, of course, take into account the failure's nature and duration.

OMP will be given notice and a reasonable opportunity to remedy any "substantial failure" before EPA's withdrawal. If there is a disagreement between Parties over whether a "substantial failure" exists, the Parties will use the dispute resolution mechanisms identified in Section 9 of this Agreement. The EPA and the Commonwealth of Pennsylvania retain their discretion to use existing enforcement authorities, including withdrawal or termination of this Project, as appropriate. OMP retains any existing rights or abilities to defend itself against any enforcement actions, in accordance with applicable procedures.

## **10.2 Procedures**

The Parties agree that the following procedures will be used to withdraw from or terminate the Project before the expiration of the Project term. They also agree that the implementing mechanism(s) will provide for withdrawal or termination consistent with these procedures.

1. Any party that wants to terminate or withdraw from the Project is expected to provide written notice to the other Parties at least sixty (60) days before the withdrawal or termination.

2. If requested by any party during the sixty (60) day period noted above, the dispute resolution proceedings described in this Agreement may be initiated to resolve any dispute relating to the intended withdrawal or termination. If, following any dispute resolution or informal discussion, a party still desires to withdraw or terminate, that party will provide written notice of final withdrawal or termination to the other Parties. If any agency withdraws or terminates its participation in the Agreement, the remaining agencies will consult with OMP to determine whether the Agreement should be continued in a modified form, consistent with applicable Federal or State law, or whether it should be terminated.
3. The procedures described in this Section apply only to the decision to withdraw or terminate participation in this Agreement. Procedures to be used in modifying or rescinding any legal implementing mechanisms will be governed by the terms of those legal mechanisms and applicable law. It may be necessary to invoke the implementing mechanism's provisions that end authorization for the Project (called "sunset provisions") in the event of withdrawal or termination.

#### **11. *Compliance After the Project is Over***

The Parties intend that there be an orderly return to compliance upon completion, withdrawal from, or termination of the Project. The following process will be used to return to compliance:

##### **11.1 Orderly Return to Compliance with Deferred Regulations, if the Project Term is Completed and Not Extended**

If, after an evaluation, the Project is terminated because the term has ended, OMP will return to compliance with all deferred requirements by the end of the Project term, unless the Project is amended or modified in accordance with Section 7 of this Agreement (Amendments or Modifications). OMP is expected to anticipate and plan for all activities to return to compliance sufficiently in advance of the end of the Project term. OMP may request a meeting with EPA and/or PADEP to discuss the timing and nature of any actions that OMP will be required to take. The Parties should meet within thirty (30) days of receipt of OMP's written request for such a discussion. During this meeting, the Parties will discuss in reasonable, good faith, which of the requirements deferred under this Project will apply after termination of the Project.

##### **11.2 Orderly Return to Compliance with Deferred Regulations in the Event of Early Withdrawal or Termination**

In the event of a withdrawal or termination not based on the end of the Project term, and where OMP has made efforts in good faith, the Parties to the Agreement will determine an interim compliance period to provide

sufficient time for OMP to return to compliance with any regulations deferred under the Project. The interim compliance period will extend from the date which EPA or PADEP provides written notice of final withdrawal or termination of the Project in accordance with Section 10 of this Agreement. By the end of the interim compliance period, OMP will comply with the deferred standards set forth in 40 CFR Part 262, 264, 265 and/or 270 and the corresponding PADEP regulations under 25 PA Code as applicable. During the interim compliance period, EPA and/or PADEP may issue an order, permit, or other legally enforceable mechanism establishing a schedule for OMP to return to compliance with deferred regulations as soon as practicable. This schedule cannot extend beyond 6 months from the date of withdrawal or termination. OMP intends to be in compliance with all applicable Federal, State, and local requirements as soon as is practicable, as will be set forth in the new schedule.

## **12. Effective Date and Signatories**

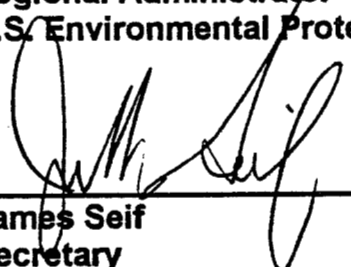
### **12.1 Effective Date**

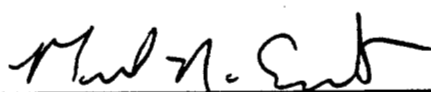
This Final Project Agreement between Ortho-McNeil Pharmaceutical, the U.S. Environmental Protection Agency and the Commonwealth of Pennsylvania Department of Environmental Protection to permit OMP to operate a high-temperature catalytic oxidation process to treat radioactive / hazardous LLMW generated by Research and Development activities on-site is effective after signature by the undersigned.

### **12.2 Signatories**

The Signatories to this Agreement are as follows:

  
\_\_\_\_\_  
**Bradley Campbell**  
**Regional Administrator**  
**U.S. Environmental Protection Agency – Region III**

  
\_\_\_\_\_  
**James Seif**  
**Secretary**  
**Pennsylvania Department of Environmental Protection**

  
\_\_\_\_\_  
**Michael R. Esposito**  
**Lead Environmental Engineer**  
**Ortho-McNeil Pharmaceutical**

## **STATEMENT OF BELIEFS**

As a member of the Johnson & Johnson Family of Companies, Ortho-McNeil Pharmaceutical, and all of our employees, adhere to ***Our Credo***, a system of values and a statement of principles and beliefs which guide our business in all that we do. ***Our Credo*** makes commitments to being a responsible corporate citizen to the communities in which we live and work and to the world community as well, to protecting the environment and natural resources, to developing innovative programs, and to providing high quality products and services for our patients at a reasonable cost. In pursuing this Project XL initiative, Ortho-McNeil Pharmaceutical believes we are upholding the Johnson & Johnson ***Credo*** pledge to our customers, employees, communities and stockholders.

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX A**

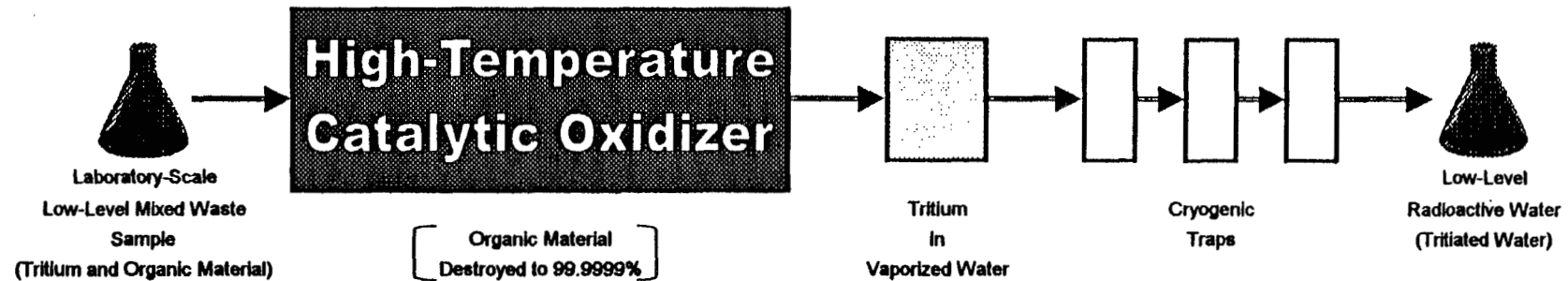
**SIMPLIFIED SCHEMATIC  
HIGH-TEMPERATURE CATALYTIC OXIDATION PROCESS**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

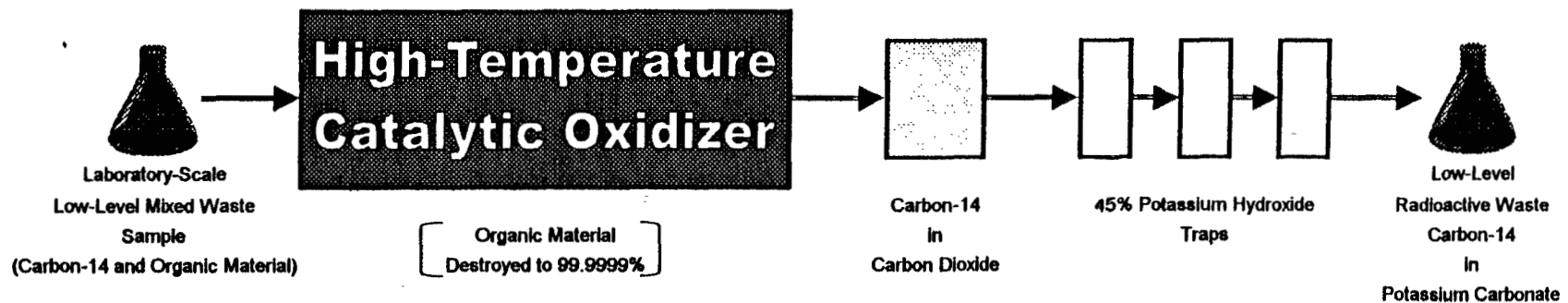
## Appendix A

### Simplified Schematic High-Temperature Catalytic Oxidation Process

#### 1) Tritium Sample



#### 2) Carbon-14 Sample



**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX B**

**LIST OF HAZARDOUS ORGANIC COMPOUNDS AND  
CORRESPONDING DESTRUCTION REMOVAL EFFICIENCIES**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**



## APPENDIX B

### List of Hazaedous Organic Compounds and Corresponding Destruction Removal Efficiency

Organic Compound	% DRE	# 9s
Acetone	99.999991%	7
Cyclohexane	99.999991%	7
Toluene - Methanol - Water, 20:70:10, v/v/v	99.99999%	7
Isopropanol	99.999997%	7
Ethanol	99.999997%	7
Methanol	99.99999%	7
Tetrahydrofuran	99.999997%	7
Ethyl Acetate	99.999998%	7
Ether	99.99999%	7
Acetonitrile - Water, 50:50, v/v	99.999996%	7
CH <sub>2</sub> Cl <sub>2</sub> - Methanol - Water, 40:50:10, v/v/v	CH <sub>2</sub> Cl <sub>2</sub> = 99.99998%	6
	Methanol = 99.9998%	5
CHCl <sub>3</sub> - Methanol - Water, 40:50:10, v/v/v	CHCl <sub>3</sub> = 99.999997%	7
	Methanol = 99.9997%	5
1,4-Dichlorobenzene - Methanol - Water, 10:80:10, v/v/v	pDCB = 99.999%	5
	Methanol = 99.99999%	7
Isopropanol - Water, 50:50, v/v	99.99999%	7
Tetrahydrofuran - Water, 50:50, v/v	99.999991%	6
Triethylamine - Water - Acetic acid, 10:80:10, v/v/v	99.999% (1 ppm Det. Limit)	5
Dimethylformamide	99.9996%	5
Pyridine - Water, 20:80, v/v	99.9996%	5
Phenol - Water, 5:95, w/w	99.9994%	5
Formaldehyde - Water, 10:90, w/w	99.99993%	6
Isooctane - Water - Isopropanol, 20:70:10, v/v/v	Isooctane = 99.99993%	6
Isooctane - Pump Oil - Isopropanol, 30:20:50, v/v/v	Isooctane = 99.99995%	6
Toluene - Water, 20:80, v/v	99.999996%	7
Formula 989 - Water, 40:60, v/v	No Organics	N/D

**Experimental Conditions:** Destruction was completed using a 1.5" ID catalyst tube containing 100 g of 0.5% platinum catalyst coated on alumina beads and heated to 750 °C. Sample feed rate was 1 ml/min, using oxygen flowing at 3.1 L/min. The system was allowed to equilibrate for 1.5 hours before collection of samples. The samples were collected from the effluent stream in a series of three dry ice-cooled traps and transferred to clean, dry 20 mL vials (Chem series 300, certified) equipped with 0.125 mm septa. The vials were completely filled in each case and no air space at the top of the vial was permitted. The vials were refrigerated at 0-4 °C until analyzed. Analyses were performed using a Hewlett Packard model 5890 gas chromatograph equipped with a flame ionization detector. A 30 meter (0.53 mm ID) Supelco VOCOL™ 3 µm capillary column was used. Samples of 2 µL were analyzed using the following temperature program: hold an initial temperature of 30 °C for 15 min., then a linear heating ramp to 200 °C at a rate of 20 °C/minute. The final temperature was maintained for 35 minutes. The carrier gas was He and the flow rate was 4.6 mL/min. The injector was operated with a 3:1 split ratio at 230 °C. The detector was operated at 230 °C, with air at a flow rate of 400 mL/min and H<sub>2</sub> at 30 mL/min. No detector make-up gas was used. The detector attenuation was set to zero. The detection limit for the method was typically about 50 ppb.

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX C**

**EPA ACCEPTANCE LETTER OF OMP PROJECT XL PROPOSAL  
FOR FINAL PROJECT AGREEMENT NEGOTIATIONS**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103

December 28, 1999

Michael Esposito  
Acting Manager of Environmental Engineering  
Ortho-McNeil Pharmaceutical, Inc.  
Welsh & McKean Rds  
Spring House, PA 19477-0000

**Re: EPA Acceptance of Ortho-McNeil Pharmaceutical Project XL Proposal (On-Site Treatment of Low-Level Mixed Wastes) for Final Project Agreement Negotiation**

Dear Mr. Esposito:

EPA is pleased to inform you that the U. S. Environmental Protection Agency ("EPA") has selected Ortho-McNeil Pharmaceutical's ("OMP's") XL proposal as a potential Project XL pilot. EPA congratulates you on your selection and thanks you and the rest of the OMP staff for your hard work on getting the proposal approved.

EPA invites you now to work with EPA staff, members of the Pennsylvania Department of Environmental Protection ("PADEP"), and appropriate stakeholders on the next stage of your XL project – developing a draft Final Project Agreement ("FPA"). While this letter does not represent final EPA approval of the project, Agency staff both at headquarters and at Region III believe your proposal has significant merit and look forward to working with you to develop your project further.

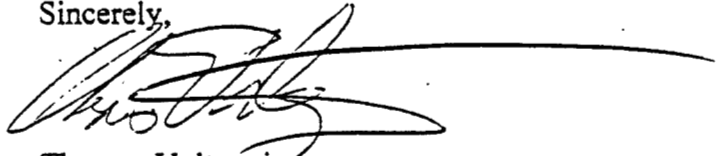
Your proposal requested relief from certain RCRA permitting requirements for an on-site bench scale catalytic oxidation unit that treats relatively small quantities of low-level mixed wastes (i.e., a waste that includes both radioactive material and RCRA hazardous waste). EPA understands that in treatability studies conducted in compliance with the RCRA regulations, the catalytic oxidation process demonstrated greater than 99.999% efficiency in the destruction of the organic component and yielded a low-level radioactive waste stream that can be solidified and landfilled at an NRC-licensed low-level waste facility.

EPA's interest in your proposal stems from its conclusion that this XL proposal has the potential to result in superior environmental performance in several respects. First, it appears that OMP's continued deployment of its catalytic oxidation process will make it easier to create a uniform low level radioactive waste stream whose radioactivity would be amenable to recycling

Again, EPA thanks you for your participation in Project XL and looks forward to working with your team to develop the FPA and implement this project. EPA has assembled an Agency-wide team to work with you and your stakeholders in the next phase of the project. This team will be led by Charles Howland in Region III (215-814-2645) and Mitch Kidwell at EPA Headquarters (202-260-2515). Please feel free to contact them if you have any questions.

Once the FPA is signed the Ortho-McNeil XL Project will become an official XL pilot. The Agency appreciates OMP's commitment to innovative projects that improve our system of environmental protection. If you have any questions or need any assistance in expediting the development and review of your Final Project Agreement, please do not hesitate to call.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Thomas Voltaggio', with a long horizontal line extending to the right.

Thomas Voltaggio  
Deputy Regional Administrator

cc: Rick Shipman, PADEP  
Betsy Ullrich, NRC

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX D**  
**NEWSPAPER ARTICLES ON THE  
ORTHO-McNEIL PROJECT**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

## ► L. GWYNEDD Firm explores waste disposal

By LAUREN KEATLEY  
Correspondent

LOWER GWYNEDD — Ortho-McNeil scientists are seeking final federal approval for a new way to treat hazardous waste at their pharmaceutical facility.

Ortho lead environmental engineering manager Michael Esposito told township supervisors Tuesday night about new technology that will also be explained to the public at a meeting Feb. 28.

The meeting, at 6 p.m. at Ortho's site on McKean Road, will help to explain the process, which is in final-project agreement with the U.S. Environmental Protection Agency.

Representatives from the EPA, the state's department of environmental protection, and national and local environmental groups will attend.

"We also want hear the public's input and concerns, such as what kind of controls they think there should be," said Esposito.

Esposito explained that Ortho's research and development group in Spring House developed a process in which used, radioactive isotopes are destroyed in a "bench-top furnace when it is heated to a high temperature."

Esposito said the "destruction is 99.999999 percent efficient."

A gaseous form of the radioisotope is condensed to radioactive water, he said.

No emissions are released into the air, as is the case with current destruction methods.

The process has been used as part of a treatability study since 1996 and the technology is shared with pharmaceutical firms worldwide, he said.

# Ortho-McNeil outlines disposal system for radioactive wastes

By Don Fleishman  
Correspondent

Only a half-dozen Lower Gwynedd residents and township officials attended a meeting at Ortho-McNeil Pharmaceutical Monday night to hear about a new treatment for hazardous and radioactive waste generated at Ortho-McNeil's Spring House labs.

None voiced surprise or concern that radioactive materials are used at the lab on McKean Road, nor did they object to the on-site treatment of mixed radioactive and hazardous waste that was the subject of the meeting.

The radioactivity was described as "less than that used in a hospital in the treatment of prostate cancer, for example," by Michael Esposito, Ortho-McNeil's lead environmental engineer at the lab, who hosted the meeting. The source of the radioactivity is tritium and carbon-14, two naturally-occurring radioactive substances.

Ortho-McNeil uses the radioisotopes as tracers in its development of new drugs. The radioactivity helps to determine that a drug being studied is expelled from the body of test subjects, Esposito explained.

Although the waste treatment process development by Ortho-McNeil scientists was presented as new, it actually has been in use at the lab since January 1996. Prior to that, the waste was hauled away by truck to a Tennessee site where it was incinerated and radioactivity was released into the atmosphere.

It's the elimination of that radioactivity venting to the atmosphere that makes Ortho-McNeil's process so interesting that the U.S. Environmental Protection Agency (EPA) has agreed to accept it as an EPA Project XL pilot, granting Ortho-McNeil relief from some of the onerous and expensive permitting requirements associated with the disposal of the radioactive and hazardous waste.

Ortho-McNeil's process, a high-tem-

perature catalytic oxidation process, reportedly destroys virtually all of the hazardous waste, which is an organic compound, a methanol solvent, and captures all of the radioactivity in the form of low-level radioactive carbon dioxide and water. None of it goes into the atmosphere.

The water currently is trucked off-site for disposal elsewhere.

Burial as a solid in South Carolina is one method used to dispose of it, but Esposito said that facility is scheduled to close in two to three years.

If the Ortho-McNeil process continues to prove to be as safe and thorough as it seems, it could be used anywhere similar waste is generated—by pharmaceutical companies, the electric power industry, research institutes, university labs, hospitals, and more.

Ortho-McNeil believes wide-spread use of its process would produce a steady stream of uniform radioactive water which would lend itself to commercial recycling

of the tritium in it, solving the disposal headache.

Ortho-McNeil has not patented its process but will make it available to others to reduce the amount of radioactivity being released into the atmosphere.

In addition to that environmental benefit, Ortho-McNeil's process also saves money — another incentive for its adoption.

Using the process, instead of paying for hazardous waste disposal, has saved Ortho-McNeil's parent company, Johnson and Johnson, more than \$2 million in the last two years alone, according to Esposito.

Neighbors don't have to worry that the on-site treatment unit at Ortho-McNeil will be large, like the trash-to-steam plant at Plymouth Meeting.

Although the amount of waste to be treated is about one ton per month, the oxidation unit is small. It was described as bench-top in size.

Charles B. Howland, senior regional

assistant counsel for the federal Environmental Protection Agency (EPA) described it as the size of a suitcase.

The volume of radioactive water produced is small, too. Larry Weaner, a senior research fellow at the R.W. Johnson Pharmaceutical Research Institute (PRI) at Spring House, and one of the scientists who developed the process, described the amount as varying from "10-20 drops to less than a quart in a month, but not every month."

Attendees at the meeting included Lower Gwynedd Township Manager Larry Comunale and police Chief Ken Bright; representatives of the Wissahickon Valley Watershed Association and a neighboring business; and several residents.

Another public meeting may be held in three or four months to present EPA's agreement with Ortho-McNeil and get public comment on it, Esposito said, and fact sheets will be produced from time to time to keep the community informed.



**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX E**  
**TREATABILITY STUDY ANNUAL REPORT**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

## 1999 TREATABILITY STUDY ANNUAL REPORT

### II FACILITY INFORMATION:

- a. Company: Ortho-McNeil Pharmaceutical  
Welsh & McKean Roads  
Spring House, PA 19477
- b. EPA ID No.: PAD000731471
- c. Point of Contact: Michael Esposito  
Lead Environmental Engineer  
Ph (215) 628-7920  
Fax (215) 628-7853

### III SUMMARY OF 1999 TREATABILITY STUDIES:

#### a. *Name, Address and EPA ID Number of Generator of Waste Samples -*

All waste samples were generated by Ortho-McNeil Pharmaceutical

Company Name: Ortho-McNeil Pharmaceutical  
Company Address: Welsh & McKean Roads  
Spring House, PA 19477

EPA ID No.: PAD000731471

#### b. *Types, by Process, of Treatability Studies Conducted -*

A total of 11 samples of "mixed waste," with a total volume of 9,870 mL and a total activity of 1049.95 mCi, were subject to 7 treatability studies during 1999. All treatability studies were conducted utilizing a high-temperature catalytic oxidation process to destroy the organic components of the "mixed waste" in order to reclassify the waste as a low-level radioactive waste for disposal.

See attached 1999 Treatability Study Summary (Attachment B)

#### c. *Names, Address and EPA ID Number of Persons For Whom Studies Have Been Conducted -*

All treatability studies were conducted for Ortho-McNeil Pharmaceutical

Company Name: Ortho-McNeil Pharmaceutical  
Company Address: Welsh & McKean Roads  
Spring House, PA 19477

EPA ID No.: PAD000731471

d. *Total Quantity of Waste in Storage Each Day -*

See attached 1999 Daily Inventory (Attachment A)

e. *Quantity and Types of Waste Subjected to Treatability Studies -*

See attached 1999 Treatability Study Summary (Attachment B)

f. *Date each Treatability Study was Conducted -*

See attached 1999 Treatability Study Summary (Attachment B)

g. *Final Disposition of Unused Samples/Residues from Each Treatability Study -*

See attached 1999 Treatability Study Summary (Attachment B)

III] 2000 TREATABILITY STUDIES FORECAST:

a. Estimate of Number of Studies to be Conducted - 5 to 8 studies

There are currently 2 samples (20 mL, 20 mCi) in inventory (generated 10/13/99) awaiting introduction into the treatability study. An approximate 6 to 10 more samples are expected to be generated during 2000. Some of these samples may be combined before being introduced into the treatability study, therefore, it is estimated that 5 to 8 studies will be conducted during 2000.

b. Amount of Waste Expected to be used in Treatability Studies - 6000 to 10000 mL

There are currently 2 samples (20 mL) in inventory awaiting introduction into the treatability study. Another 6 to 10 samples at approximately 1000 mL each are expected to be generated during 2000. Therefore, it is estimated that 6000 to 10000 mL will be used in treatability studies during 2000.

Ortho-McNeil Pharmaceutical  
Spring House, Pennsylvania

3/14/2000

**1999 TREATABILITY STUDY  
ANNUAL REPORT**

**ATTACHMENT A**

**1999 TREATABILITY STUDY  
DAILY INVENTORY**

# 1999 TREATABILITY STUDY DAILY INVENTORY

Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)
January	1	1	50	300	February	1	1	50	300	March	1	1	50	300
January	2	1	50	300	February	2	1	50	300	March	2	1	50	300
January	3	1	50	300	February	3	1	50	300	March	3	1	50	300
January	4	1	50	300	February	4	1	50	300	March	4	1	50	300
January	5	1	50	300	February	5	1	50	300	March	5	1	50	300
January	6	1	50	300	February	6	1	50	300	March	6	1	50	300
January	7	1	50	300	February	7	1	50	300	March	7	1	50	300
January	8	1	50	300	February	8	1	50	300	March	8	1	50	300
January	9	1	50	300	February	9	1	50	300	March	9	1	50	300
January	10	1	50	300	February	10	1	50	300	March	10	1	50	300
January	11	1	50	300	February	11	1	50	300	March	11	1	50	300
January	12	1	50	300	February	12	1	50	300	March	12	1	50	300
January	13	1	50	300	February	13	1	50	300	March	13	1	50	300
January	14	1	50	300	February	14	1	50	300	March	14	1	50	300
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January	16	1	50	300	February	16	1	50	300	March	16	1	50	300
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January	26	1	50	300	February	26	1	50	300	March	26	1	50	300
January	27	1	50	300	February	27	1	50	300	March	27	1	50	300
January	28	1	50	300	February	28	1	50	300	March	28	1	50	300
January	29	1	50	300	February	29	1	50	300	March	29	1	50	300
January	30	1	50	300						March	30	1	50	300
January	31	1	50	300						March	31	1	50	300

# 1999 TREATABILITY STUDY DAILY INVENTORY

Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)
April	1	1	50	300	May	1	1	50	300	June	1	1	50	300
April	2	1	50	300	May	2	1	50	300	June	2	1	50	300
April	3	1	50	300	May	3	1	50	300	June	3	1	50	300
April	4	1	50	300	May	4	1	50	300	June	4	1	50	300
April	5	1	50	300	May	5	1	50	300	June	5	1	50	300
April	6	1	50	300	May	6	1	50	300	June	6	1	50	300
April	7	1	50	300	May	7	1	50	300	June	7	1	50	300
April	8	1	50	300	May	8	1	50	300	June	8	1	50	300
April	9	1	50	300	May	9	1	50	300	June	9	1	50	300
April	10	1	50	300	May	10	1	50	300	June	10	1	50	300
April	11	1	50	300	May	11	1	50	300	June	11	1	50	300
April	12	1	50	300	May	12	1	50	300	June	12	1	50	300
April	13	1	50	300	May	13	1	50	300	June	13	1	50	300
April	14	1	50	300	May	14	1	50	300	June	14	1	50	300
April	15	1	50	300	May	15	1	50	300	June	15	1	50	300
April	16	1	50	300	May	16	1	50	300	June	16	1	50	300
April	17	1	50	300	May	17	1	50	300	June	17	1	50	300
April	18	1	50	300	May	18	1	50	300	June	18	1	50	300
April	19	1	50	300	May	19	1	50	300	June	19	1	50	300
April	20	1	50	300	May	20	1	50	300	June	20	1	50	300
April	21	1	50	300	May	21	1	50	300	June	21	1	50	300
April	22	1	50	300	May	22	1	50	300	June	22	1	50	300
April	23	1	50	300	May	23	1	50	300	June	23	1	50	300
April	24	1	50	300	May	24	1	50	300	June	24	2	640.0	307.746
April	25	1	50	300	May	25	1	50	300	June	25	2	800.0	304.900
April	26	1	50	300	May	26	1	50	300	June	26	2	800.0	304.900
April	27	1	50	300	May	27	1	50	300	June	27	2	800.0	304.900
April	28	1	50	300	May	28	1	50	300	June	28	4	900.0	467.000
April	29	1	50	300	May	29	1	50	300	June	29	1	50	300
April	30	1	50	300	May	30	1	50	300	June	30	0	0	0
					May	31	1	50	300					

# 1999 TREATABILITY STUDY DAILY INVENTORY

Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)
July	1	0	0.0	0.000	August	1	1	1430	32.854	September	1	0	0	0
July	2	0	0.0	0.000	August	2	1	934.0	21.694	September	2	0	0	0
July	3	0	0.0	0.000	August	3	1	934.0	21.694	September	3	0	0	0
July	4	0	0.0	0.000	August	4	1	318.0	7.834	September	4	0	0	0
July	5	0	0.0	0.000	August	5	1	100.0	2.464	September	5	0	0	0
July	6	0	0.0	0.000	August	6	1	0	0	September	6	0	0	0
July	7	1	3010.0	12.094	August	7	0	0	0	September	7	0	0	0
July	8	1	2753.0	10.860	August	8	0	0	0	September	8	0	0	0
July	9	1	2270.0	8.542	August	9	0	0	0	September	9	0	0	0
July	10	1	2270.0	8.542	August	10	0	0	0	September	10	0	0	0
July	11	1	2270.0	8.542	August	11	0	0	0	September	11	0	0	0
July	12	1	2270.0	8.542	August	12	0	0	0	September	12	0	0	0
July	13	1	2270.0	8.542	August	13	0	0	0	September	13	0	0	0
July	14	1	2270.0	8.542	August	14	0	0	0	September	14	0	0	0
July	15	1	2270.0	8.542	August	15	0	0	0	September	15	0	0	0
July	16	1	2270.0	8.542	August	16	0	0	0	September	16	0	0	0
July	17	1	2270.0	8.542	August	17	1	208.0	187.000	September	17	0	0	0
July	18	1	2270.0	8.542	August	18	0	0	0	September	18	0	0	0
July	19	1	1940.0	6.958	August	19	0	0	0	September	19	0	0	0
July	20	1	1595.0	5.302	August	20	0	0	0	September	20	0	0	0
July	21	1	1157.0	3.200	August	21	0	0	0	September	21	0	0	0
July	22	1	659.0	0.810	August	22	0	0	0	September	22	0	0	0
July	23	1	3179.0	72.206	August	23	0	0	0	September	23	0	0	0
July	24	1	3179.0	72.206	August	24	0	0	0	September	24	0	0	0
July	25	1	3179.0	72.206	August	25	0	0	0	September	25	0	0	0
July	26	1	2816.0	64.039	August	26	0	0	0	September	26	0	0	0
July	27	1	2287.0	52.136	August	27	0	0	0	September	27	0	0	0
July	28	1	1886.0	43.114	August	28	0	0	0	September	28	0	0	0
July	29	1	1430.0	32.854	August	29	0	0	0	September	29	0	0	0
July	30	1	1430.0	32.854	August	30	0	0	0	September	30	0	0	0
July	31	1	1430.0	32.854	August	31	0	0	0	September	31	0	0	0

# 1999 TREATABILITY STUDY DAILY INVENTORY

Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)	Month	Day	Total Samples	Quantity (in mL)	Activity (in mCi)
October	1	0	0	0	November	1	2	20	20	December	1	2	20	20
October	2	0	0	0	November	2	2	20	20	December	2	2	20	20
October	3	0	0	0	November	3	2	20	20	December	3	2	20	20
October	4	0	0	0	November	4	2	20	20	December	4	2	20	20
October	5	0	0	0	November	5	2	20	20	December	5	2	20	20
October	6	0	0	0	November	6	2	20	20	December	6	2	20	20
October	7	0	0	0	November	7	2	20	20	December	7	2	20	20
October	8	0	0	0	November	8	2	20	20	December	8	2	20	20
October	9	0	0	0	November	9	2	20	20	December	9	2	20	20
October	10	0	0	0	November	10	2	20	20	December	10	2	20	20
October	11	0	0	0	November	11	2	20	20	December	11	2	20	20
October	12	0	0	0	November	12	2	20	20	December	12	2	20	20
October	13	2	20	20	November	13	2	20	20	December	13	2	20	20
October	14	2	20	20	November	14	2	20	20	December	14	2	20	20
October	15	2	20	20	November	15	2	20	20	December	15	2	20	20
October	16	2	20	20	November	16	2	20	20	December	16	2	20	20
October	17	2	20	20	November	17	2	20	20	December	17	2	20	20
October	18	2	20	20	November	18	2	20	20	December	18	2	20	20
October	19	2	20	20	November	19	2	20	20	December	19	2	20	20
October	20	2	20	20	November	20	2	20	20	December	20	2	20	20
October	21	2	20	20	November	21	2	20	20	December	21	2	20	20
October	22	2	20	20	November	22	2	20	20	December	22	2	20	20
October	23	2	20	20	November	23	2	20	20	December	23	2	20	20
October	24	2	20	20	November	24	2	20	20	December	24	2	20	20
October	25	2	20	20	November	25	2	20	20	December	25	2	20	20
October	26	2	20	20	November	26	2	20	20	December	26	2	20	20
October	27	2	20	20	November	27	2	20	20	December	27	2	20	20
October	28	2	20	20	November	28	2	20	20	December	28	2	20	20
October	29	2	20	20	November	29	2	20	20	December	29	2	20	20
October	30	2	20	20	November	30	2	20	20	December	30	2	20	20
October	31	2	20	20						December	31	2	20	20



**1999 TREATABILITY STUDY  
ANNUAL REPORT**

**ATTACHMENT B**

**1999 TREATABILITY STUDY  
SUMMARY**

# 1999 TREATABILITY STUDY SAMPLE SUMMARY

Sample Number	Date Generated	Volume (in mL)	Sample Composition (proportions based on 100% total)										Other		Radionuclide	Activity (mCi)
			Water	TFE	EtOH	ACN	MeOH	MDC	THF	hexane	Misc	Other	Material			
13954-149	1/15/1998	50	45		1.9	45		8					0.1	TFA	3-H	300
13109-21	6/24/1999	590	45		1.7	47	1.7		10.2						3-H	7.746
13109-22	6/25/1999	750	50			50							0.1	TFA	3-H	4.9
13109-24-A	6/26/1999	750	60				10		30						3-H	123
13109-24-B	6/26/1999	60	60				40						0.1	TFA	3-H	24
13109-24-C	6/26/1999	40	30	30						10					3-H	20
13109-30	7/7/1999	3410										5	80	pump oil	14-C/3-H	14.014
13109-39	7/23/1999	3700										5	75	pump oil	14-C/3-H	86.290
13109-59	8/17/1999	500							6	94					14-C	450
13109-64	10/13/1999	5			100									levamisole	3-H	5
13109-65	10/13/1999	15											100	toluene	14-C	15

TOTAL VOLUME IN STORAGE IN 1999:

9870 mL

TOTAL ACTIVITY IN STORAGE IN 1999:

1049.95 mCi

## Treatability Study Summary:

1. A total of 11 samples, with a total volume of 9,870 mL and a total activity of 1049.95 mCi, were introduced into 7 treatability studies during 1999.
2. All treatability studies conducted utilized high-temperature catalytic oxidation to destroy the organic components of the "mixed waste."
3. Studies commenced on the following dates:

Date	Samples
24-Jun-99	13109-21
25-Jun-99	13109-22
28-Jun-99	13109-24-A, B, and C
29-Jun-99	13954-149
7-Jul-99	13109-30
23-Jul-99	13109-39
17-Aug-99	13109-59

# 1999 TREATABILITY STUDY SUMMARY

## Process: High-Temperature Catalytic Oxidation

Date of Study	Total Volume (in mL)	Total Activity (in mCi)	Samples Treated (from sample summary)	Sample Composition (proportions based on 100% total)										Disposition of Residue	
				Water	TFE	EtOH	ACN	MeOH	MDC	THF	hexane	Misc	Other		
24-Jun-99	590	7.746	13109-21	45		1.7	47	1.7			10.2				discarded to drain
25-Jun-99	750	4.9	13109-22	50			50							0.1	discarded to drain
28-Jun-99	850	167	13109-24-A, B, and C	60	1	1	2	9			27				discarding to drain in progress
29-Jun-99	50	300	13954-149	45		1.9	45		8	5				0.1	discarding to drain in progress
7-Jul-99	3410	14,014	13109-30							5	80			15	discarded to drain
23-Jul-99	3700	86.29	13109-39							5	75			25	discarded to drain
17-Aug-99	500	450	13109-59							6	94				bottled for commercial disposal

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX F**

**EXPLANATION OF UNITS FOR  
MEASUREMENT OF RADIOACTIVITY**

**ORTHO-McNEIL PHARMACEUTICAL  
Spring House, Pennsylvania**

## Esposito, Mike [OMP] (SH)

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From: LaVake, Thomas [PRI]  
Sent: Tuesday, April 25, 2000 3:34 PM  
To: Esposito, Mike [OMP] (SH)  
Cc: Weaner, Larry [PRI]; Hoerr, David [PRI]; Smock, Curtis [PRI]  
Subject: Project XL information

Mike:

A brief explanation of the curie (Ci):

Curie - a unit of radioactivity that represents  $2.22 \times 10^{12}$  disintegrations per minute (dpm). Think of the curie as you think of grams being a unit of mass.

To help the EPA relate the concept of curie to radiation exposure, the following information may be useful:

- 1 microcurie ( $\mu\text{Ci}$ ) =  $10^{-6}$  Ci
- 1 millicurie (mCi) =  $10^{-3}$  Ci
- Annual occupational whole body dose limit = 5,000 mrem
- Annual dose limit for member of the public = 100 mrem
- The NRC effluent air concentration for H-3 is  $2 \times 10^{-8}$   $\mu\text{Ci}/\text{ml}$  (which means that if you were to breathe this air continuously over the course of a year, your dose would be equivalent to 50 millirem).
- The NRC effluent air concentration for C-14 is  $6 \times 10^{-8}$   $\mu\text{Ci}/\text{ml}$  (which, again, means that if you were to breathe this air continuously over the course of a year, your dose would be equivalent to 50 millirem).
- The effluent air concentration released at PRI in 1999 for H-3 was  $3.55 \times 10^{-12}$   $\mu\text{Ci}/\text{ml}$  and for C-14 was  $3.03 \times 10^{-11}$ . If anyone was on top of our Research Building and they inhaled this air (and for this exercise we will say that the air contains both H-3 and C-14 - as a worst case scenario) continuously over the course of 1999, their dose would have been 0.034 mrem.
- Comparison - Typical mouth x-ray (depending on number of images) = 2 -20 mrem
- Comparison - Typical chest x-ray 10~20 mrem
- Comparison - Radiation dose from transcontinental flight 2-3 mrem.

Our effluent air monitoring is conducted whenever volatile forms of radioactive materials are being utilized and there is a possible release to the environment.

If you have any questions, let me know. I'll be in my office in Raritan tomorrow from 10-12 if you want to call me from Philadelphia.

Best regards,

**Thomas LaVake**

Worldwide Radiation Safety - Safety and Industrial Hygiene

Phone: 908-704-4239

Fax: 908-707-9211

E-mail: [tlavake@prius.jni.com](mailto:tlavake@prius.jni.com)

J&J Radiation Safety Information Available at: <http://jw.jcus.jni.com/trg/sih/radiation/healthphysics.htm>

[Code of Federal Regulations]  
[Title 10, Volume 1, Parts 1 to 50]  
[Revised as of January 1, 2000]  
From the U.S. Government Printing Office via GPO Access  
[CITE: 10CFR20.1005]

[Page 299]

## TITLE 10--ENERGY

### COMMISSION

#### PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION--Table of Contents

##### Subpart A--General Provisions

#### Sec. 20.1005 Units of radioactivity.

✓ For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

(a) One becquerel = 1 disintegration per second ( $s^{-1}$ ).

(b) One curie =  $3.7 \times 10^{10}$  disintegrations per second =  $3.7 \times 10^{10}$  becquerels =  $2.22 \times 10^{12}$  disintegrations per minute.

[56 FR 23391, May 21, 1991; 56 FR 61352, Dec. 3, 1991]

[Co Federal Regulations]  
 [Title, Volume 1, Parts 1 to 50]  
 [Revised as of January 1, 2000]  
 From U.S. Government Printing Office via GPO Access  
 [CITE 10CFR20.1004]  
 [Page 29-299]

# TITLE 10--ENERGY

## COMMISSION

### PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION--Table of Contents

#### Subpart A--General Provisions

#### Sec. 20.1004 Units of radiation dose.

(a) Definitions. As used in this part, the units of radiation dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).

(b) As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in table 1004(b).1.

Table 1004(b).1--Quality Factors and Absorbed Dose Equivalencies

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent \a\
X-, gamma, or beta radiation.....	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge.....	20	0.05
Neutrons of unknown energy.....	10	0.1
High-energy protons.....	10	0.1

\a\ Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

(c) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from table 1004(b).2 to convert a measured tissue dose in rads to dose equivalent in rems.

Table 1004(b).2--Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic Neutrons

Neutron energy (MeV)	Quality factor \a\ (Q)	Fluence per unit dose equivalent \b\ (neutrons cm <sup>-2</sup> rem <S >1</SUP>)
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(thermal)..... 2.5 x 10 <sup>-8</sup> 2 980 x 10 <sup>-6</sup>

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1 x 10 <sup>-7</sup>	2	980 x 10 <sup>-6</sup>
1 x 10 <sup>-6</sup>	2	810 x 10 <sup>-6</sup>
1 x 10 <sup>-5</sup>	2	810 x 10 <sup>-6</sup>
1 x 10 <sup>-4</sup>	2	840 x 10 <sup>-6</sup>
1 x 10 <sup>-3</sup>	2	980 x 10 <sup>-6</sup>
1 x 10 <sup>-2</sup>	2.5	1010 x 10 <sup>-6</sup>
1 x 10 <sup>-1</sup>	7.5	170 x 10 <sup>-6</sup>
5 x 10 <sup>-1</sup>	11	39 x 10 <sup>-6</sup>
1	11	27 x 10 <sup>-6</sup>
2.5	9	29 x 10 <sup>-6</sup>
5	8	23 x 10 <sup>-6</sup>
7	7	24 x 10 <sup>-6</sup>
10	6.5	24 x 10 <sup>-6</sup>
14	7.5	17 x 10 <sup>-6</sup>
20	8	16 x 10 <sup>-6</sup>
40	7	14 x 10 <sup>-6</sup>
60	5.5	16 x 10 <sup>-6</sup>
1 x 10 <sup>-2</sup>	4	20 x 10 <sup>-6</sup>
2 x 10 <sup>-2</sup>	3.5	19 x 10 <sup>-6</sup>
3 x 10 <sup>-2</sup>	3.5	16 x 10 <sup>-6</sup>
4 x 10 <sup>-2</sup>	3.5	14 x 10 <sup>-6</sup>

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\a\ Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

\b\ Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.



**EPA PROJECT XL**

**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX G**

**DETAILED DESCRIPTION OF THE  
CATALYTIC OXIDATION PROCESS**

**ORTHO-McNEIL PHARMACEUTICAL**  
Spring House, Pennsylvania

## A PROTOTYPE HIGH-TEMPERATURE CATALYTIC OXIDATION PROCESS FOR MIXED WASTE IN A PHARMACEUTICAL RESEARCH LABORATORY

David C. Hoerr and Larry E. Weaver  
The R. W. Johnson Pharmaceutical Research Institute  
Chemical Development Department  
Welsh and McKean Roads  
Spring House, PA 19477-0776 USA

### ABSTRACT

A high-temperature catalytic oxidation process that destroys the organic components in mixed radioactive-hazardous organic streams as they are generated in the laboratory has been developed and tested. The process can accommodate both organic and aqueous mixtures. Gas chromatographic analysis of the collected effluent stream following destruction shows that a wide variety of hazardous organic chemicals are effectively removed. Destruction and removal efficiencies are at least 99.999% under the operating conditions.

### INTRODUCTION

In our laboratory, carbon-14 and tritium-labeled compounds are synthesized for use in the development of potential new therapeutic compounds. The syntheses generate MBq to GBq (mCi to Ci) quantities of mixed waste containing a wide variety of hazardous organic materials. These consist of contaminated aqueous mixtures and various organic solvents, intermediates, and reagents used in the synthesis and purification of the labeled samples. The organic components include hydrocarbons, halocarbons, acetonitrile, alcohols, ethers, and aromatic compounds. A single preparation involves volumes ranging from 50 mL to several liters.

In order to avoid long-term storage of radioactive hazardous materials in our facility, we investigated the use of a high-temperature oxidation process to destroy the organic components in these samples as they are generated. Under the conditions used, a liquid mixture is completely reacted with oxygen or air at high temperature in the presence of an oxidation catalyst (1). Water and the radiolabeled reaction products, either tritiated water or carbon-14-labeled carbon dioxide, are then recovered free of hazardous organic chemicals (2) by the use of an appropriate trapping method. The trapped samples may be recycled through the process to achieve a higher destruction efficiency if the first pass was not effective. Depending upon the composition of the sample, by-products such as hydrochloric acid or nitric acid may be generated during oxidation and these materials can also be trapped and recovered.

Equipment for the destruction of hazardous organics is commercially available, and processes for handling radioactive (waste) materials have been patented (3). However, these are not suitable for the small-scale destruction of samples containing large quantities of radioactivity. The apparatus used in this study was constructed from readily available components and is convenient for use in a laboratory environment. Over 1800 hours of development and operating experience has shown that the apparatus effectively destroys a wide variety of materials in a safe operation.

### EXPERIMENTAL METHODS

#### Apparatus Description

Samples are passed through an electrically heated, stainless steel tube packed with a platinum catalyst. The catalyst tube is a 1.7 cm long stainless steel tube with a wall thickness of 4.8 mm and an inside diameter of 28.6 mm. The catalyst bed is prepared as shown in Fig. 1. The entrance to the bed is packed with 15 g of untreated alumina pellets followed by 100 g of 0.5% platinum metal coated on 3.2 mm pellets of gamma alumina (Strem

Chemicals, Newburyport, MA). The section containing the platinum catalyst is about 152 mm long. The final portion of the tube is packed with 430 g of untreated alumina pellets. The pellets are held in place by the use of a small coiled roll of nickel tubing pressed in place at the bed entrance and supported at the bed exit by the end flange.

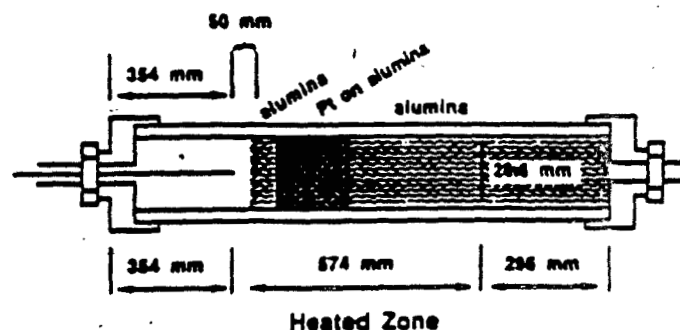


Fig. 1. Sketch of the catalyst bed.

Heat is provided using a commercially available tube furnace, equipped with three separately controlled heating zones. The interior volume of the furnace has a diameter of 7.6 cm and is 57.4 cm long. Liquid samples are pumped into the heated catalyst tube through a 0.51 mm ID stainless steel sample inlet tube using a positive displacement pump. The pump, which provides a steady and pulseless flow, incorporates a high pressure limit switch to stop the pump should the sample inlet tube become blocked during processing. Either air or oxygen can be used as the oxidant gas (4). However, to achieve effective trapping of carbon-14-labeled carbon dioxide, the lower flow rate employed in the oxygen process is optimal. Oxygen is supplied from a laboratory cylinder and regulated to a delivery pressure of 35 kPa (5 psi).

A safety monitoring system, used to give basic on/off control of the pump, monitors both high and low gas pressure and temperature during operation. Pressure sensors with a range of zero to 100 kPa (15 psi) are incorporated at the delivery head and the system exit. Thermocouples, located near the head of the catalyst bed but outside of the catalyst tube and in the tube exit, are used to monitor temperature conditions in the system. An unsafe condition, such as no oxygen flow, excess back pressure or high temperature, is quickly detected and causes the monitor to turn off electric power to the sample pump. The system is placed into a safe standby mode until reset by an operator.

Tritiated water, radioactive carbon dioxide and other by-products can be effectively collected using appropriate

pressure-tight trapping. For tritium-labeled samples, three dry-ice cooled cold traps are used in series. This is accomplished by passing the hot effluent stream into a 2-liter glass flask, which is cooled with dry ice. Uncollected vapors are passed through a water-cooled reflux condenser and then through two dry-ice cooled 1 L round bottom flasks connected in series. Greater than 99% trapping efficiency is obtained for tritiated water with this system. For carbon-14-labeled materials, the exit gases from the oxidation tube are first cooled by passage through a water-cooled glass heat exchanger and then through a series of four 1 L gas scrubbing bottles. The bottles are charged with a 45% solution of potassium hydroxide, which is dilute enough to solubilize the potassium carbonate that is produced when completely saturated with carbon dioxide. Greater than 99% trapping efficiency is obtained with this arrangement for radioactive carbon dioxide. Additional traps can readily be added to either of the above systems to increase the capacity or obtain greater recovery of the radioactive by-products.

### Operational Parameters

On start up, the temperature of the tube furnace is set at 750°C. The oxygen flow-rate is set to 3.1 L/min for a feed rate of 1 mL/min of organic material. A correspondingly higher oxygen flow rate is necessary if the organic throughput is increased. The sample feed rate is set between 1 and 5 mL/min depending on the heat content of the sample. Pure organic compounds and solvents are normally oxidized at a feed rate of 1-2 mL/min, depending on the heat content of the sample. The temperature is allowed to increase up to a maximum of 850°C. In practice, samples are blended to allow organic and aqueous samples to be oxidized as mixtures. For mixtures where the water content is 50% or greater, the feed rate can be increased and 2-2.5 L of the blended sample can be processed over an 8-hour day.

### Analytical Methodology

Destruction efficiencies for organic materials were determined by collection of the effluent stream and analysis by gas chromatography. Samples were processed for a minimum of two hours to ensure that a large sample size was collected and that steady processing conditions were achieved during the test. Three dry ice-cooled traps were used to recover all of the condensable material. Samples were sealed in completely full IChem 300 series (certified) vials and refrigerated at 0-4°C until analyzed. Assay for residual organic material in the collected samples was performed using a Hewlett Packard Model 5890 gas chromatograph equipped with a flame ionization detector and a split-splitless injector. Analyses were completed with a 30-meter VOCOL™ capillary column operated with helium as the carrier gas and at a flow rate of 4.2 mL/min. Following injection, the column was held at 30°C for 15 minutes and then temperature programmed to increase at a rate of 20°C/minute to a final temperature of 200°C. This temperature was maintained for 35 minutes. The detector and injector were operated at 230°C. A sample volume of 2  $\mu$ L was used, and the sample split ratio was 3:1. The detector response was determined to be linear up to 10 ppm. The detection limit for the method was 50 ppb.

In addition to GC analyses, oxidation efficiency was monitored by measuring the carbon monoxide levels using a Dräger miniPac T3 carbon monoxide monitor. The monitor was calibrated using a certified calibration gas mixture of 251 ppm CO in air. The instrument has a measuring range of 0 to 2000 ppm for CO.

## RESULTS AND DISCUSSION

The apparatus is constructed primarily of stainless steel, with Model used for the connecting tubing and fittings between the exit of the catalyst tube and the trapping system. Because highly acidic by-products are generated, it is necessary to assure that no aqueous solutions are condensed and remain in contact with the exit tubing. Early work with stainless steel tubing showed that very rapid corrosion occurred on contact with the condensed liquids. To prevent condensation from occurring, the tubing connecting the catalyst tube with the traps is heated to 120°C by the use of a heating tape. This maintains the effluent stream in a vaporized form until it enters the glass trapping system.

The configuration and positions of the sample inlet tube, catalyst, and alumina in the catalyst tube are important for obtaining high destruction efficiency with a minimum of soot and partial oxidation products generated for several different classes of compounds. The best catalyst position found to date is close to the sample inlet tube with the approximate dimensions shown in Fig. 1. When the catalyst is placed, for example, at the far end of the heated zone, low levels of soot are observed when acetone and hydrocarbons are oxidized.

The operating temperature range of the furnace was selected to be several hundred degrees above the autoignition temperature of the various compounds and solvents used in laboratory experiments. Studies with acetone, toluene, and cyclohexane showed that at lower operating temperatures partial oxidation products (products of incomplete combustion, 5) were observed. At an initial temperature of 300°C the following compounds are identified by GC in the oxidation product of cyclohexane: cyclohexane (430 ppm), either benzene or cyclohexene (300 to 500 ppm), toluene (24 ppm), cyclohexanol (4 ppm), cyclohexenone (6 ppm), and naphthalene (4 ppm). At 750°C destruction efficiencies are increased significantly and only naphthalene and cyclohexenone are detected in concentrations less than 100 ppb.

The rate of oxygen flow through the system was determined not to be a critical factor as long as at least 1.4 equivalents of oxygen are present. Oxygen requirements were determined by measuring the level of carbon monoxide produced as the flow of oxygen was varied during the oxidation of methanol, isopropanol, hexane, and acetone. The sample feed rate was held constant at 1 mL/min, and the temperature was 750°C. When the oxygen flow rate is decreased from nearly 8 to 2.4 L/min no carbon monoxide is observed (Fig. 2). When the flow rate is further decreased to 1.6 L/min, the carbon monoxide level increases to greater than 2000 ppm for isopropanol, acetone, and hexane. With methanol, no CO is detected at a flow rate of 1.6 L/min, but significant levels of CO are observed at an oxygen flow rate of 1.1 L/min. Based on these data, the optimum oxygen flow rate was established as 3.1 L/min for pure organic substances processed at a feed rate of 1 mL/min. In practice, oxygen flow rates are adjusted to between 3.1 and 4.7 L/min depending on the sample feed rate. The curves shown in Fig. 2 are typical for a system that is operating properly, and testing for CO is performed routinely to confirm acceptable catalyst efficiency.

Two catalysts were investigated to determine the most effective catalyst for this process. The 0.5% platinum catalyst coated on alumina pellets was selected based on the high oxidation efficiencies obtained for a wide range of materials and on the long lifetime of the catalyst. In general use, catalyst lifetimes are between 200 and 500 hours with no gradual decrease in efficiency over time. The catalyst is very resistant to poisoning at these temperatures and only a few substances have been found to reduce its effectiveness. Compounds containing chlorine, nitrogen, and sulfur can all be processed with high oxidation

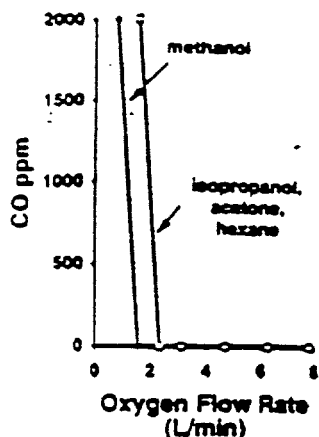


Fig. 2. Dependence of carbon monoxide on oxygen flow rate. Sample were processed at 1 mL/min, 750°C over 100 g of 0.5% Pt coated on alumina catalyst, with 3.1 L of oxygen flow per minute.

efficiencies. In the case of phosphorous containing compounds, the catalyst appears to be slowly coated with a compound that causes the catalyst to become ineffective after processing only small quantities of material. Figure 3 shows the effect on carbon monoxide levels as the oxidation efficiency of the catalyst is reduced. In this case, the data were obtained by measuring the carbon monoxide levels while varying the flow rate of air, rather than oxygen. The system was operated at 750°C with a sample feed rate of 1 mL/min. The optimum flow rate for air had been determined to be 12.4 L/min with fresh catalyst. After processing a quantity of HPLC buffer containing about thirty grams of monobasic triethylammonium phosphate, the efficiency of the catalyst was measured by evaluating the CO levels while processing isopropyl alcohol and hexane. With isopropyl alcohol, a minimum of 500 ppm of CO was detected and with hexane 50 ppm was observed under optimum operating conditions. The catalyst activity, however, was fully restored by washing the phosphorous-containing material from the catalyst bed using dilute aqueous sodium hydroxide solution followed by a water rinse at room temperature. The catalyst bed and tube were then dried at the operating temperature for several hours before use.

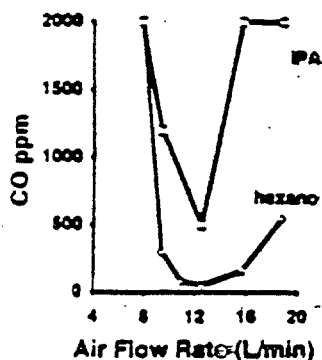


Fig. 3. Carbon monoxide observed with inhibited catalyst. Samples were processed at 1 mL/min, 750°C, over 100 g 0.5% Pt coated on alumina catalyst using air at 12.4 L/min.

The destruction and removal efficiency of the apparatus was evaluated for various organic substances and the results are shown in Table I. Pure samples such as simple alcohols (methanol, ethanol, and isopropanol), acetone, ethyl acetate, ether, tetrahydrofuran, and acetonitrile are readily processed at a feed

rate of 1 mL/min and an oxygen flow rate of 3.1 L/min. The destruction and removal efficiency is at least 99.99999% (7 nines). The observed destruction and removal efficiency for the pure samples is not affected by diluting the samples to a 50:50 mixture by volume with water. No residual organics are observed by gas chromatographic analysis to the detection limit of about 50 ppb. When the samples are further diluted to a concentration of 1% in water, the measured DRE is 99.9997% (5 nines). The lower DRE value is a result of the algebraic effect of reducing the total organic component processed without a corresponding decrease in the detection limit. No residual organic substance is detected for these samples. The observed DRE is not affected by increasing the feed rate from 1 to 5 mL/min.

Test samples of halogenated substances mixed with 50% methanol and 10% water by volume were processed using the conditions described above. The methanol and water cosolvents were added to assure that generated chlorine was converted to hydrochloric acid (6). Methylene chloride and chloroform are both destroyed to 6 nines or greater, however, the oxidation efficiency for methanol in the mixture decreases to only 5 nines. The observed decrease may be attributed to an inhibition effect of the generated HCl on catalytic activity (6). A solution of 10% 1,4-dichlorobenzene (pDCB) in 80% methanol with 10% water is oxidized to 99.9998% destruction and removal efficiency (7), with about 0.1 ppm of the unreacted substrate collected in the effluent stream. In this sample, methanol was destroyed to 7 nines DRE.

Hydrocarbons such as cyclohexane are oxidized with a DRE greater than 7 nines, but aromatic compounds (8) proved difficult to oxidize cleanly in the absence of water or isopropanol. The destruction of 100% toluene using the above conditions resulted in a heavy formation of soot with no CO present in the effluent stream. Dilution to 20% by volume with isopropanol or water is required to avoid the generation of soot. For carbon-14-labeled aromatic samples, where the addition of an organic cosolvent is a disadvantage because of the generation of additional carbon dioxide that must be trapped, oxidation can be completed using 20% emulsions of the aromatic compound in water to provide 5 to 7 nines DRE with no extra carbon loading for the caustic traps. Toluene, processed in this emulsion form, is destroyed to 7 nines or greater. Similarly, pyridine has a DRE of 99.9996% (6 nines) when oxidized as a 20% solution in water. Phenol, which was processed as a 5% solution in water, gave a destruction and removal efficiency of 99.9994% (5 nines). The phenol was not totally removed and 0.2 ppm was detected in the collected condensate.

Vacuum pump oil is readily processed by blending with 30% isooctane (iO) and 50% isopropanol. The results show that isooctane and isopropanol are well destroyed (6 and 7 nines DRE, respectively) and no organics are detected in the recovered oxidation product. Undiluted pump oil cannot be processed directly due to pumping limitations, but can be oxidized as an emulsion formed with water. The use of an emulsion is also required to process other samples such as LSC cocktail fluids, which otherwise undergo pyrolysis on injection and plug the sample inlet tube.

## SUMMARY

A catalytic oxidation process that operates on a laboratory scale to destroy the organic components in radioactive-hazardous organic streams as they are generated has been developed and tested. To date, the radiosynthesis laboratory has processed a total of 965 mCi (35.7 GBq) of tritiated materials in a total matrix of 31.7 Kg in a variety of types of hazardous organic materials. A total of 28.8 mCi (1.07 GBq) of carbon-14-labeled

TABLE I

Destruction and Removal Efficiency for Various Organic Compounds. The Samples Were Oxidized as Pure Materials and in Mixtures. Sample Feed Rates Were Either 1 or 5 mL/min.

POHC	% DRE	# 9s	Conc.	Matrix	Feed Rate (mL/min)
methanol (MeOH)	99.999990%	7	100%	pure	1
ethanol	99.999997%	7	100%	pure	1
isopropanol (IPA)	99.999997%	7	100%	pure	1
IPA	99.99999%	7	50%	water	1
IPA	99.9997%	5	1%	water	1
IPA	99.9997%	5	1%	water	5
diethyl ether	99.99999%	7	100%	pure	1
ethyl acetate	99.999998%	7	100%	pure	1
acetone	99.999991%	7	100%	pure	1
tetrahydrofuran (THF)	99.999997%	7	100%	pure	1
THF	99.99994%	7	50%	water	1
THF	99.9997%	5	1%	water	1
THF	99.9997%	5	1%	water	5
acetonitrile	99.999991%	7	50%	water	1
acetonitrile	99.9997%	5	1%	water	1
acetonitrile	99.9997%	5	1%	water	5
dichloromethane (DCM)	99.99998%	6	40%	MeOH-water	1
chloroform (CHCl <sub>3</sub> )	99.999997%	7	40%	MeOH-water	1
MeOH	99.9998%	5	50%	DCM-water	1
MeOH	99.9997%	5	50%	CHCl <sub>3</sub> -water	1
1,4-dichlorobenzene (DCB)	99.9998%	5	10%	MeOH-water	1
MeOH	99.99999%	7	80%	DCB-water	1
cyclohexane	99.999991%	7	100%	pure	1
toluene	99.99999%	7	20%	MeOH-water	1
toluene	99.999997%	7	20%	water	1
pyridine	99.99996%	6	20%	water	1
phenol	99.9994%	5	5%	water	1
isooctane (iO)	99.99993%	6	30%	vacuum pump oil-IPA	1
IPA	99.999995%	7	50%	vacuum pump oil-iO	1

materials have been oxidized in a total sample mass of 23.8 Kg. No radioactive wastes containing hazardous organic chemicals have been generated.

#### ACKNOWLEDGEMENTS

The authors are grateful for the contributions of David Diorio of the Ortho-McNeil Pharmaceutical Corporation and Les Souther of Scott Instruments for the safety monitoring system.

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## A PRACTICAL APPROACH TO THE DESTRUCTION OF RADIOACTIVE ORGANIC MIXTURES

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### INTRODUCTION

In the pharmaceutical industry, carbon-14 and tritium-labeled compounds are synthesized for use in drug metabolism studies as a part of the development of potential new therapeutic compounds. The syntheses generate mixed waste containing MBq to GBq (mCi to Ci) quantities of radioactivity in a wide variety of hazardous organic materials. In the USA, the alternatives for dealing with this waste are either long-term storage or expensive commercial incineration. We have been investigating the use of a high-temperature oxidation process to destroy the organic components (Weaner and Hoerr 1994, Hoerr and Weaner 1995), and in the case of tritium, recovering the radioactivity as tritium gas for reuse. Under the conditions used, a liquid mixture is completely reacted with oxygen or air at high temperature in the presence of an oxidation catalyst (Spivey 1987, Kosusko and Nunez 1990). Depending on the waste composition, throughput rates of 0.5 to 2.5 L/day can be obtained. Effluent from the totally enclosed process is completely trapped, preventing any environmental release of radioactivity. The collected tritium-containing effluent can then be processed to recover pure tritium gas. In this paper, we discuss the results obtained to date for the oxidation process. Over 2400 hours of development and operating experience at several sites has shown that the apparatus effectively destroys a wide variety of materials with minimal sample pretreatment in a safe operation.

### EXPERIMENTAL METHODS

#### Apparatus Description

Although the system has been previously described (Hoerr and Weaner 1995), a brief overview is provided here. The process takes place in a heated, 61 cm-long seamless

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stainless steel tube packed with 0.5% platinum on alumina catalyst. Heat is provided using a tube furnace equipped with three separately controlled heating zones. Liquid samples are blended and pumped into the heated catalyst tube using a pair of HPLC pumps. An electronic safety supervisor system monitors critical pressures and temperatures during operation and turns the pumps off if an unsafe condition develops.

Tritiated water, radioactive carbon dioxide and other by-products can be effectively collected using appropriate pressure-tight trapping. For tritium-labeled samples, a series of three dry ice-cooled traps are used. Process effluent containing acidic byproducts or carbon dioxide- $^{14}\text{C}$  is scrubbed through a series of four gas washing bottles containing a 45% solution of potassium hydroxide.

#### Operational Parameters

On start up, the temperature of the tube furnace is set at 750 °C and the temperature is allowed to increase up to a maximum of 850 °C while operating. The oxygen flow rate is set to 3.1 L/min for a feed rate of 1 mL/min of organic material, and a correspondingly higher oxygen flow rate is used as the organic throughput is increased. To optimize throughput, organic samples are blended with aqueous samples using the two pumps. The higher water content not only moderates the heat evolved but in many cases increases the destruction efficiency. For mixtures where the water content is 75% or greater, a feed rate of 5 to 6 mL/minute is attainable.

#### Analytical Methodology

Oxidation efficiency is determined by measuring the carbon monoxide levels using a Dräger miniPac T3 hand-held CO monitor and by GC analysis. The method used for GC analysis has been previously described (Hoerr and Weaner 1995). In addition, GC analysis was also performed using headspace sampling with a capillary column and a flame ionization detector.

#### RESULTS AND DISCUSSION

A 0.5% platinum catalyst coated on alumina pellets (Strem Chemicals, Newburyport, MA) was selected based on the high oxidation efficiencies obtained for a wide range of materials and on the long lifetime of the catalyst. Catalyst lifetimes are between 200 and 500 hours, and no gradual decrease in efficiency has been observed. The catalyst is resistant to poisoning at these temperatures and only a few substances have been found to reduce its effectiveness. Mixtures containing chlorine and nitrogen, known catalyst poisons, can be processed with high oxidation efficiencies. However, the catalyst becomes coated and ineffective after oxidizing just a few grams of phosphorus and must be periodically restored. To accomplish this, the phosphorous-containing material is washed from the catalyst bed at room temperature using dilute aqueous sodium hydroxide. This treatment restores the catalyst to full activity. Sulfur-containing compounds cause a slow degradation of the packing material and result in a noticeable



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increase in back pressure, but have no effect on the oxidation efficiency. Eventually the catalyst bed must be replaced.

The destruction and removal efficiency (DRE, the ratio of the mass of substrate removed by the process to the total substrate processed) of the process was determined by GC analysis of the collected effluents, and the results are summarized in Table 1.

Table 1.

SUBSTRATE	RESIDUE	DRE
Acetone, Acetonitrile, Chloroform, Cyclohexane, Diethyl Ether, Ethanol, Ethyl Acetate, Isopropanol, Methanol, Methylene Chloride, Pyridine, Tetrahydrofuran, Toluene, Trimethylbenzene	None Detected	99.999% to 99.99999%
Phenol	0.2 ppm	99.999%
p-Dichlorobenzene	1 ppm	99.999%

For most samples, no residual organic substrates are observed by gas chromatographic analysis down to the detection limit of about 50 to 100 ppb. This includes pure samples and mixtures, processed with and without water. The range of the DRE values reported is a result of reducing the net mass of the organic component when processed as a dilute aqueous solution, without a corresponding increase in the sensitivity of the GC assay.

However, several substrates proved difficult to oxidize completely with a single pass through the process. Halogenated substances were processed in the presence of water to assure that any generated  $\text{Cl}_2$  was converted to  $\text{HCl}$  (Rossin and Farris, 1993), and chloroform and methylene chloride are oxidized with at least 99.9999% DRE. However, a solution of 10% 1,4-dichlorobenzene (pDCB) in 80% methanol with 10% water is oxidized to 99.999% DRE, with about 1 ppm of pDCB collected in the effluent stream. Although hydrocarbons such as cyclohexane are cleanly oxidized with at least 99.99999% DRE, the oxidation of pure toluene (Barresi *et al.* 1992) results in copious production of soot, even though no CO is detected in the effluent. When diluted to 20% by volume with isopropanol or water, no soot is produced and toluene is destroyed to at least 99.99999%. Phenol, processed as a 5% solution in water, was not totally destroyed as 0.2 ppm was detected in the collected condensate.

Radioactive waste samples, containing complex mixtures of organic compounds, were also processed with great effectiveness, and typically, no residual organic substrates were detected in the effluent. The DREs for the hazardous organic components were calculated based on the analytical detection limits, and DREs of at least 99.999% to 99.99999% were observed for acetonitrile, ethanol, methanol, methylene chloride, and trimethylbenzene. Sample flow rates ranged from 1 to 6 mL/minute. Due to the acidic byproducts obtained with halogenated materials, the effluent was trapped using aqueous



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45% potassium hydroxide (KOH). Based on in-line tritium monitoring, at least 99.99995% of the tritium was removed by the KOH traps. The trapping efficiency of the dry ice-cooled traps was determined to be at least 99.98%.

#### SUMMARY

A catalytic oxidation process that operates on a laboratory scale to destroy the organic components in radioactive-hazardous organic streams as they are generated has been developed and tested. To date, 1350 TBq (36.5 Ci) of tritiated materials have been oxidized in a total sample matrix of 43 Kg. A total of 1.07 GBq (28.8 mCi) of  $^{14}\text{C}$ -labeled materials have been oxidized in a total sample mass of 23 Kg. All radioactive effluents, principally tritiated water and carbon dioxide- $^{14}\text{C}$ , were effectively recovered using simple trapping systems.

#### ACKNOWLEDGMENTS

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## TRITIUM RECOVERY FROM TRITIATED LIQUIDS

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Liquids which have been used in the production or analysis of tritiated compounds become contaminated with tritium and need to be classified as mixed wastes to reflect their organic and radioactive hazards. Disposal of mixed wastes with activities exceeding a few tens of GBq/L (hundreds of mCi/L) becomes economically prohibitive. In addition the generator retains liability for the buried waste should any escape to the environment in the future. Combustion of many liquids to form water for disposal offers limited relief because the combustion products must retain the original mixed waste classification in compliance with the so called 'Derived from' rule. Furthermore the volume of disposable liquid generally increases during the combustion process to aggravate the problem for the generator. As a consequence, many generators have stored their mixed wastes on site or in facilities under their control while searching for a solution.

Facilities to recovery tritium from a broad range of mixed waste liquids including oil are under development at Ontario Hydro. The underlying process comprises three major steps: high efficiency conversion of liquids to water, reduction of water to hydrogen and reclamation of tritium from the effluent hydrogen stream. Details of the combustion studies carried out at the R. W. Johnson and Ontario Hydro facilities are described in a companion paper at this conference. Patented tritium reclamation processes developed at Ontario Hydro over the past 15 years in support of fission and fusion applications are detailed in the open literature. The process is expected to offer two major advantages: de-listing of the liquids from the mixed waste category and elimination of generator liability once the mixed waste is processed. Studies to date using sample wastes from a number of pharmaceutical firms demonstrate that their typical streams can be processed at practical rates while retaining organic emissions well within EPA guidelines and total tritium emissions to the environment negligible. Organic destruction and removal efficiencies typically exceed 6 nine's; tritium releases if detectable remain below  $10^4$  of the processed inventory. As an aside, the involvement of pharmaceutical companies in this study has indirectly addressed practical issues of waste segregation, RSO buy-in, packaging and shipping within those firms.

This paper will discuss the process technology, present preliminary water reduction results, outline isotope separation performance parameters and touch on the mechanics of shipping mixed waste.

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX H**  
**OUTREACH EFFORTS**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

Ortho McNeil XL Proposal Meeting  
October 20, 1999

Agenda

1. Introductions
2. Description/demonstration of high temperature catalytic oxidation process (Ortho)
3. Proposed Superior Environmental Performance presented by Ortho XL Proposal (Ortho)
4. Nature of NRC regulation of process (Ortho, NRC)
5. Status of EPA Reauthorization of Pa. RCRA Program (EPA, PADEP)
6. Possible Regulatory Relief (EPA/PADEP) (Group)
  - a. Exclusion
  - b. Conditional exemption
  - c. Potential impact of proposed LLMW Rule
  - d. Delisting
  - e. Other
7. Next steps (Group)
  - a. Additional information needed to review proposal
  - b. Timetable for issue resolution

**Project XL Meeting**  
**Wednesday October 20, 1999**  
**Attendance Sheet**

Name	Affiliation
Beth Termini	EPA Region 3, Office of Reinvention
Charles Howland	EPA Region 3, Office of Reinvention
Mitch Kidwell	EPA HQ, Office of Reinvention
Josh Lewis	EPA HQ, Office of Solid Waste
Gary Gross	EPA Region 3, RCRA
Steve Donohue	EPA Region 3
Rick Shipman	Pennsylvania Department of Environmental Protection
Jim Roof	Pennsylvania Department of Environmental Protection
Carl Spadero	Pennsylvania Department of Environmental Protection
Iona Shambaky	PADEP - Radiation Protection
Ron Furlan	Pennsylvania Department of Environmental Protection
Nancy Sheperd	Lawrence Berkely National Laboratory
Besty Ullrich	US Nuclear Regulatory Commission Region 1
Dave Hoerr	Principle Scientist, RWJ Pharmaceutical Research Institute
Tom LaVake	Radiaton Safety Officer, Johnson & Johnson
Al Iannuzzi	Johnson & Johnson Worldwide Environmental Affairs
Mike Esposito	Lead Environmental Engineer, Ortho-McNeil Pharmaceutical

# **Project XL**

## **Stakeholders Meeting**

**Monday February 28, 2000 - 6:00 pm**

**Ortho-McNeil Pharmaceutical**

### **AGENDA**

- ◆ Welcome / Introduction (Linda Manning)
- ◆ Project XL Overview (EPA)
- ◆ Facility Overview (OMP)
- ◆ Current Environment (OMP)
- ◆ Proposal Background (OMP)
- ◆ Proposal Overview (OMP)
- ◆ Basis for Proposal (OMP)
- ◆ Proposal Advantages (OMP)
- Our Goals (OMP)
- ◆ Next Steps (EPA)
- ◆ Regulators Comments (EPA & PADEP)
- ◆ Q & A

## Project XL Stakeholders Meeting

Monday February 28, 2000

### Attendance Sheet

Name	Affiliation
Ed Stanley	Lower Gwynedd Township Resident / Industrial Compact Member
David Froehlich	Executive Director, Wissahickon Valley Watershed Association
Linda Callegari	Lower Gwynedd Township Resident / CAC Member
Tom Enright	Industrial Compact Member / Aventis Corp.
Ken Bright	Police Chief, Lower Gwynedd Township
Larry Comunale	Township Manager, Lower Gwynedd Township
Ramesh Belani	Pennsylvania Department of Environmental Protection
Beth Termini	EPA, Region 3
Charles Howland	EPA, Region 3
Dave Hoerr	Principle Scientist, RWJ Pharmaceutical Research Institute
Larry Weaner	Research Fellow, RWJ Pharmaceutical Research Institute
Tom LaVake	Radiation Safety Officer, Johnson & Johnson
Mike Esposito	Lead Environmental Engineer, Ortho-McNeil Pharmaceutical
Linda Manning	Marasco-Newton Group
Don Flatham	Ambler Gazette

## **Project XL Stakeholders Meeting**

**Monday February 28, 2000**

### **Invitation List**

#### ***Township Officials:***

- |   |   |
|---|---|
| <p>1 Al Comly<br/>Fire Marshal<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> <p>3 Larry Comunale<br/>Township Manager<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> <p>5 Kate Harper<br/>Supervisor<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> | <p>2 Ken Bright<br/>Police Chief<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> <p>4 Charlene Stevens<br/>Assistant Township Manager<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> <p>6 Edward Brandt<br/>Supervisor<br/>Lower Gwynedd Township<br/>1130 N. Bethlehem Pike<br/>P.O. Box 625<br/>Spring House, PA 18477</p> |
|---|---|

#### ***Lower Gwynedd Township Industrial Compact Members***

- |  |  |
|--|--|
| <p>7 Joe Dolby<br/>Rohm &amp; Haas Company<br/>Research Laboratories<br/>727 Norristown Road<br/>Spring House, PA 19477</p> <p>9 Jerry Reed<br/>Henkel Corporation<br/>300 Brookside Avenue<br/>Ambler, PA 19002</p> | <p>8 Tom Enright<br/>Rhône-Poulenc Inc.<br/>P.O. Box 406<br/>500 Railroad Ave.<br/>Ambler, PA 19002</p> <p>10 Ron Falusy<br/>Moore Products Co.<br/>Sumneytown Pike<br/>Spring House, PA 19477</p> |
|--|--|

#### ***Lower Gwynedd Township Citizens***

- |   |   |
|---|---|
| <p>11 Harvey Salwen<br/>817 Brushtown Road<br/>Gwynedd Valley, PA 19437</p> | <p>12 Edward Stanley<br/>Plymouth Road<br/>Gwynedd Valley, PA 19437</p> |
|---|---|



***Local Environmental Groups***

- |   |   |
|---|---|
| 13 Bruce Jones<br>Plant Superintendent<br>Ambler Wastewater Treatment Plant<br>122 East Butler Ave.<br>Ambler, PA 19002 | 14 Dave Froehlich<br>Executive Director<br>Wissahickon Valley Watershed Association<br>12 Morris Road<br>Ambler, PA 19002 |
|---|---|

***Local Community Groups***

- Rohm & Haas Community Advisory Council  
15 Christine Miller, Rohm & Haas Public Relations

***Members -***

- |                      |                 |                    |
|----------------------|-----------------|--------------------|
| 16 Dwight Dundore    | 22 Nada Cail    | 27 Linda Callegari |
| 17 Richard Kline     | 23 Quentin Fehr | 28 Leola Hubbard   |
| 18 Russell Long      | 24 James Harper | 29 Herbert Levy    |
| 19 Virginia B. Modla | 25 Paul Langer  | 30 Carl Kollman    |
| 20 Ed Sweitzer       | 26 Anne O'Brien | 31 Pete Watson     |
| 21 Jacque Huggins    |                 |                    |

***Internal Johnson & Johnson Associates***

- |                  |   |
|------------------|---|
| 32 Tom Lavake    | J&J Radiation Safety Officer                  |
| 33 Larry Weaner  | PRI Research Fellow                           |
| 34 Dave Hoerr    | PRI Principle Scientist                       |
| 35 Robert Barnes | OMP Site Manager                              |
| 36 Dan DaCunha   | OMP Incident Commander                        |
| 37 Al Iannuzzi   | J&J Corporate Worldwide Environmental Affairs |
| 38 Brad Gardner  | J&J Corporate Worldwide Environmental Affairs |
| 39 Karl Schmidt  | J&J Corporate Worldwide Environmental Affairs |
| 40 Branda Davis  | J&J Corporate Worldwide Environmental Affairs |

***Publication Announcements***

Lower Gwynedd Township Supervisors Meeting  
Tuesday, February 15, 2000

Montgomery County Reporter  
Wednesday, February 16, 2000

Times Herald  
Friday, February 25, 2000

## **Ortho-McNeil Pharmaceutical (OMP) XL Project**

### **Environmental and Local Stakeholder Meeting Spring House, PA**

**July 18, 2000**

#### **Agenda**

#### ***Meeting Objectives:***

- To brief participants about the EPA XL Program and the history and current status of the Ortho-McNeil Pharmaceutical (OMP) XL Project
- To brief those unfamiliar with OMP's catalytic oxidation technology and discuss its use with OMP scientists
- To explain the regulatory oversight for OMP's treatment process, at present and during implementation of the XL project
- To understand different perspectives about the treatment and disposal of low-level mixed wastes from an R&D facilities

**3:30-4:00**

#### ***Welcome***

**(Ortho-McNeil welcomes stakeholders and regulators)**

#### ***Introductions***

**(Everyone introduces themselves and describes their work and experience)**

#### ***Agenda***

**(Briefly review, add or revise)**

#### ***Expectations***

**(Everyone describes why they are here and what they hope to get from the meeting)**

**4:00-4:30**

#### ***EPA Overview of Project XL***

**(EPA explains XL objectives, process, safeguards and FPA status)**

**4:30-5:00**

#### ***OMP XL Project Overview***

**(OMP gives project overview and tour of facility. Questions welcome)**

**5:00-6:00**

#### ***Discussion and next steps***

**(Time to ask and respond to questions, comments and concerns)**

**Ortho-McNeil hosts light dinner**

## **Project XL Stakeholders Meeting**

**Tuesday July 18, 2000**

### **Invitation List**

#### ***Township Officials:***

- |  |  |
|--|--|
| 1 Al Comly<br>Fire Marshal<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477           | 2 Ken Bright<br>Police Chief<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477                     |
| 3 Larry Comunale<br>Township Manager<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477 | 4 Charlene Stevens<br>Assistant Township Manager<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477 |
| 5 Kate Harper<br>Supervisor<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477          | 6 Edward Brandt<br>Supervisor<br>Lower Gwynedd Township<br>1130 N. Bethlehem Pike<br>P.O. Box 625<br>Spring House, PA 18477                    |

#### ***Lower Gwynedd Township Industrial Compact Members***

- |  |  |
|--|--|
| 7 Joe Dolby<br>Rohm & Haas Company<br>Research Laboratories<br>727 Norristown Road<br>Spring House, PA 19477 | 8 Tom Enright<br>Rhone-Poulenc Inc.<br>P.O. Box 406<br>500 Railroad Ave.<br>Ambler, PA 19002 |
| 9 Jerry Reed<br>Henkel Corporation<br>300 Brookside Avenue<br>Ambler, PA 19002                               | 10 Ron Falusy<br>Moore Products Co.<br>Sumneytown Pike<br>Spring House, PA 19477             |

#### ***Lower Gwynedd Township Citizens***

- |  |  |
|--|--|
| 11 Harvey Salwen<br>817 Brushtown Road<br>Gwynedd Valley, PA 19437 | 12 Edward Stanley<br>Plymouth Road<br>Gwynedd Valley, PA 19437 |
|--|--|

12a Larry Exner - (215) 542-0422  
415 Wyndon Road  
Ambler, PA 19002

***Local Environmental Groups***

13 Bruce Jones  
Plant Superintendent  
Ambler Wastewater Treatment Plant  
122 East Butler Ave.  
Ambler, PA 19002

14 Dave Froehlich  
Executive Director  
Wissahickon Valley Watershed Association  
12 Morris Road  
Ambler, PA 19002

***Local Community Groups***

Rohm & Haas Community Advisory Council  
15 Christine Miller, Rohm & Haas Public Relations

***Members -***

16 Dwight Dundore  
17 Richard Kline  
18 Russell Long  
19 Virginia B. Modla  
20 Ed Sweitzer  
21 Jacque Huggins

22 Nada Cail  
23 Quentin Fehr  
24 James Harper  
25 Paul Langer  
26 Anne O'Brien

27 Linda Callegari  
28 Leola Hubbard  
29 Herbert Levy  
30 Carl Kollman  
31 Pete Watson

***Internal Johnson & Johnson Associates***

32 Tom Lavake	J&J Radiation Safety Officer
33 Larry Weaner	PRI Research Fellow
34 Dave Hoerr	PRI Principle Scientist
35 Robert Barnes	OMP Site Manager
36 Dan DaCunha	OMP Incident Commander
37 Al Iannuzzi	J&J Corporate Worldwide Environmental Affairs
38 Brad Gardner	J&J Corporate Worldwide Environmental Affairs
39 Karl Schmidt	J&J Corporate Worldwide Environmental Affairs
40 Branda Davis	J&J Corporate Worldwide Environmental Affairs

## Project XL Stakeholders Meeting

Tuesday July 18, 2000

### Attendance Sheet

Name	Affiliation
Dr. Judith Johnsrud	Sierra Club, Pennsylvania Chapter
Joe Dolby	Industrial Compact Member / Rohm & Haas Corp.
Beth Termini	EPA, Region 3
Charles Howland	EPA, Region 3
Iona Shambaky	PADEP - Radiation Protection
Ron Furlan	Pennsylvania Department of Environmental Protection
Dave Hoerr	Principle Scientist, RWJ Pharmaceutical Research Institute
Larry Weaner	Research Fellow, RWJ Pharmaceutical Research Institute
Tom LaVake	Radiation Safety Officer, Johnson & Johnson
Mike Esposito	Lead Environmental Engineer, Ortho-McNeil Pharmaceutical
Robert Barnes	Site Manager, Ortho-McNeil Pharmaceutical
Catherine Allen	Marasco-Newton Group

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX I**  
**TECHNOLOGY TRANSFER EFFORTS**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**

## **APPENDIX I**

### **Ortho-McNeil Pharmaceutical Project XL Final Project Agreement**

#### **Summary of Technology Transfer Efforts**

The following is a list of presentations provided by Johnson & Johnson personnel related to the High-Temperature Catalytic Oxidation Process:

1. International Symposium on the Synthesis and Applications of Isotopes and Isotopically Labeled Compounds; June 1994; Strasbourg, France.
2. PA Pharmaceutical Environmental Managers Meeting; July 1994; King of Prussia, PA.
3. International Incineration Conference; 1995 May 8-12; Seattle, WA.
4. National Low Level Mixed Waste Workshop, Northeast Compact Region; September 12, 1995; Farmington, CT.
5. ACURI Association Annual Meeting, August 1996, Harrisburg, PA.
6. Symposium on Mixed Waste Treatment and Disposal: Oct. 24, 1996; Mystic, CT.
7. Delaware Valley Society for Radiation Safety; November 20, 1996; King of Prussia, PA.
8. Technical Symposium and Annual Meeting of the New England Chapter of the Health Physics Society; May 22, 1997; Nashua, NH.
9. Sixth International Symposium on the Synthesis and Applications of Isotopically Labeled Compounds; Philadelphia, PA, Sept. 14-18, 1997.
10. Symposium on Mixed Waste Treatment and Disposal: May 28, 1998; Ann Arbor, MI.
11. Sixteenth Northeast US Meeting of the International Isotope Society, October 29-30, 1998; Princeton, NJ.
12. Host State Technical Coordinating Committee, January 1998, Raleigh, NC.
13. Workshop to Explore the Options for Tritium and Carbon-14 Recovery from Pharmaceutical Solvents, February 22-23, 2000, Toronto, Canada.
14. Seventh International Symposium on the Synthesis and Applications of Isotopically Labeled Compounds, June 18-22, 2000, Dresden, Germany.
15. American Radiation Safety Conference and Exposition, June 25-29, 2000, Denver, Colorado.

In addition, R.W. Johnson Pharmaceutical Research Institutes have provided on-site demonstrations to almost 100 companies, organizations and individuals who have shown interest in the technology. These demonstrations included representatives from pharmaceutical companies, regulatory agencies, DOE facilities, academic institutes, research organizations, NIH, electric power industry, commercial TSDFs, and the National Tritium Labeling Facility among others.

**EPA PROJECT XL**  
**FINAL PROJECT AGREEMENT**

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC  
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTE**

**APPENDIX J**  
**NRC LICENSE**

**ORTHO-McNEIL PHARMACEUTICAL**  
**Spring House, Pennsylvania**





UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 8, 1996

R.W. JOHNSON PHARMACEUTICAL RES.INS  
ATTN: Mr. THOMAS W. LAWKE  
Radiation Safety Officer  
DIV. OF ORTHO PHARMACEUTICAL CORP.  
ROUTE 202, P.O. BOX 300  
RARITAN, NJ 08869-0602

SUBJECT: ONE-TIME EXTENSION OF LICENSE EXPIRATION DATE  
LICENSE NUMBER 29-02608-03, DOCKET NUMBER 3010814

Dear Mr. THOMAS W. LAWKE

On January 16, 1996, the Nuclear Regulatory Commission (NRC) amended its regulations in 10 CFR 30, 40, and 70 to extend the expiration date of certain byproduct, source, and special nuclear material licenses by five years (61 FR 1109). The above referenced license was extended by this rulemaking and will now expire on January 31, 2003. Your license will not be amended to show this extended date until the next routine licensing action. Until then, you may provide copies of this letter to vendors and other interested parties as evidence that the license has been extended as a result of the rule.

A extended license authorizes the same activities and contains the same limitations as it previously did. There will be no change in the frequency that the NRC inspects activities authorized by this license.

The amended rules state that in the case of licensees who are granted extensions and who have a currently pending renewal application for that extended license, the application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded. This will apply to licenses with expiration dates after July 1, 1995, for which renewal applications and the appropriate fees have been submitted and the renewal is still pending. Refunds will be mailed to licensees under separate cover.

All licensees, including those whose renewal applications were withdrawn by this rulemaking, who wish to change their radiation safety programs must request amendment of their licenses to reflect these changes. Amendment requests must include the correct amendment fee since the NRC cannot apply pending renewal refund balances toward amendment fees.

If you have any questions regarding this letter, please contact the individual below.

John D. Kinneman, Chief Branch 2 - (610) 337-5252

Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "DAC", is written over a horizontal line.

Donald A. Cool, Director  
Division of Industrial and Medical Nuclear Safety  
Office of Nuclear Materials Safety and Safeguards

**MATERIALS LICENSE**

Amendment No. 17

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

**Licensee**

1. R.W. Johnson Pharmaceutical  
Research Institute  
A Division of Ortho Pharmaceutical  
Corporation  
2. Route 202  
P.O. Box 300  
Raritan, New Jersey 08869-0602

In accordance with the letter dated  
April 30, 1993,

3. License number 29-02608-03 is amended in  
its entirety to read as follows:

4. Expiration date January 31, 1998

5. Docket or  
Reference No. 030-10814/37-09743-01

6. Byproduct, source, and/or  
special nuclear material

7. Chemical and/or physical  
form

8. Maximum amount that licensee  
may possess at any one time  
under this license

A. Any byproduct material with  
Atomic Numbers 3 through 83

A. Any

A. Not to exceed 500  
millicuries per  
radionuclide and 5 curies  
total

B. Hydrogen 3

B. Any

B. 50.0 curies

C. Carbon 14

C. Any

C. 4.0 curies

D. Iodine 125

D. Any

D. 1.0 curie

9. Authorized use

A. through D. Research and development as defined in 10 CFR 30.4, including animals studies; and for transfer to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or an Agreement State.

**CONDITIONS**

10. Licensed material may be used only at the licensee's facilities at: Ortho Pharmaceutical Corporation, U.S. Route #202 South, Raritan, New Jersey; Ortho Diagnostic Systems Inc., U.S. Route #202 North, Raritan, New Jersey; Ortho Pharmaceutical Corporation, Research Institute Farm, Route #513, Pittstown, New Jersey; Advanced Care Products, U.S. Route #1 South, North Brunswick, New Jersey; and R.W. Johnson Pharmaceutical Research Institute, Welsh and McKean Roads, Spring House, Pennsylvania.

11. A. Licensed material at the New Jersey facilities shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee at the R.W. Johnson Pharmaceutical Research Institute in Raritan, New Jersey. The licensee shall maintain records of individuals designated as users.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

29-02608-03

Docket or Reference number

030-10814/37-09743-01

Amendment No. 17

(11. continued)

**CONDITIONS**

B. Licensed material at the Pennsylvania facility shall be used by, or under the supervision of individuals designated by the Radiation Safety Committee at the R.W. Johnson Pharmaceutical Research Institute in Spring House, Pennsylvania. The licensee shall maintain records of individuals designated as users.

C. The Radiation Safety Officer for this license is Thomas W. La Vake.

12. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.

13. Experimental animals administered licensed materials or their products shall not be used for human consumption.

14. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

1. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

- (i) they contain only hydrogen 3; or
- (ii) they contain only a gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

29-02608-03

Docket or Reference number

030-10814/37-09743-01

Amendment No. 17

(15. Continued)

**CONDITIONS**

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

17. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

18. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.

19. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material".

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

29-02608-03

Docket or Reference number

030-10814/37-09743-01

Amendment No. 17

(Continued)

**CONDITIONS**

21. Radioactive waste generated under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letters dated June 26, 1992 and September 30, 1992.
22. The licensee shall not store, at the Spring House facility, licensed material contained in waste for more than two (2) years from the date the waste is put into storage or October 1, 1993, which ever is later. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage. This condition does not apply to licensed material intended for disposal by decay-in-storage pursuant to 10 CFR 35.92 or other conditions of this license.
22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - A. Application dated June 26, 1991
  - B. Letter dated January 24, 1992
  - C. Letter dated June 26, 1992
  - D. Letter dated September 25, 1992
  - E. Letter dated September 30, 1992
  - F. Letter dated April 30, 1993
  - G. Letter dated July 21, 1993
  - H. Letter dated August 5, 1993

SEP 01 1993

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For the U.S. Nuclear Regulatory Commission

By *Christopher J. Hill*  
Nuclear Materials Safety Branch  
Region I  
King of Prussia, Pennsylvania 19406